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

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2009–0558]

Security Performance (Adversary) Characteristics for Physical Security Programs for 10 CFR Part 72 Licensees

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft regulatory guide; discontinuation.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is discontinuing proposed Draft Regulatory Guide (DG), DG–5033, ''Security Performance (Adversary) Characteristics for Physical Security Programs for 10 CFR Part 72 Licensees.'' This DG was intended to support a new rule that would contain security requirements for Independent Spent Fuel Storage Installations (ISFSIs). Because the scope of the rulemaking has changed and the rule will no longer include the new requirements that DG–5033 was intended to support, the staff is discontinuing development of DG–5033.

DATES: The discontinuation of DG–5033 takes effect on May 29, 2020.

ADDRESSES: Please refer to Docket ID NRC–2009–0558 when contacting the NRC about the availability of information regarding these documents. You may obtain publicly-available information related to these documents using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2009–0558. Address questions about NRC docket IDs in *regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov*. For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public 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*. The ADAMS accession number for each document referenced (if it available in ADAMS) is provided the first time that a document is referenced.

FOR FURTHER INFORMATION CONTACT: Duane White, Office of Nuclear Security and Incident Response, telephone: 301–287–3627, email: *Duane.White@nrc.gov,* or Mekonen Bayssie, Office of Nuclear Regulatory Research, telephone: 301–415–1699, email: *Mekonen.Bayssie@nrc.gov*. Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION: The NRC is discontinuing development of DG–5033, a non-public document containing Safeguards Information (SGI). This DG was intended to support a new rule that would include new security requirements for ISFSIs. On December 18, 2007, the Commission issued SRM–SECY–07–0148, ''Independent Spent Fuel Storage Installation Security Requirements for Radiological Sabotage'' (ADAMS Accession No. ML073530119), which approved the staff's recommendation to develop new, risk informed, performance-based security requirements applicable to all ISFSI licensees to enhance existing security requirements. The Commission also approved the staff's recommendation to develop regulatory guidance (*i.e.,* DG–5033) for security scenarios for ISFSIs that would be bounded by the adversary characteristics supporting the design basis threat for radiological sabotage associated with power reactors. The staff developed DG–5033 in response and transmitted it to cleared stakeholders (*i.e.,* individuals who were subject to fingerprinting and criminal history records checks for access to SGI and had an established ''need to know'') for comment on March 21, 2011.

Subsequently, the Commission directed the staff in a non-public SRM for COMKLS–18–0003, ''Fiscal Year 2020 Budget to the Commission,'' dated August 22, 2018, to reduce the scope of the rulemaking and codify only the requirements of the security orders issued by the NRC following the terrorist attacks of September 11, 2001. As a result, the rule will no longer address security scenarios against which licensees would perform dose calculations and apply site specific radiological dose acceptance limits, which DG–5033 was intended to support. Therefore, the staff has determined that the development of DG–5033 is no longer warranted and is discontinued.

Dated: May 19, 2020.

For the Nuclear Regulatory Commission.

Thomas H. Boyce,

Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2020–11202 Filed 5–28–20; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1141

[Docket No. FDA–2019–N–3065]

RIN 0910–AI39

Tobacco Products; Required Warnings for Cigarette Packages and Advertisements; Delayed Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; delay of effective date.

SUMMARY: In accordance with an order issued by the U.S. District Court for the Eastern District of Texas, this action delays the effective date of the final rule (''Tobacco Products; Required Warnings for Cigarette Packages and Advertisements''), which published on March 18, 2020, from June 18, 2021, to October 16, 2021.

DATES: The effective date of the rule amending 21 CFR part 1141 published at 85 FR 15638, March 18, 2020, is delayed until October 16, 2021.

FOR FURTHER INFORMATION CONTACT: Courtney Smith, Office of Regulations, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New

Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, *AskCTPRegulations@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 18, 2020, the Food and Drug Administration (FDA or Agency) issued a final rule establishing new cigarette health warnings for cigarette packages and advertisements. The final rule implements a provision of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) that requires FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany new textual warning label statements. The Tobacco Control Act amends the Federal Cigarette Labeling and Advertising Act of 1965 to require each cigarette package and advertisement to bear one of the new required warnings. The final rule specifies the 11 new textual warning label statements and accompanying color graphics. Pursuant to section 201(b) of the Tobacco Control Act, the rule was published with an effective date of June 18, 2021, 15 months after the date of publication of the final rule.

On April 3, 2020, the final rule was challenged in the U.S. District Court for the Eastern District of Texas.[1] Due to the COVID–19 pandemic and its impacts, on May 8, 2020, the court granted a joint motion to govern proceedings in that case and postpone the effective date of the final rule by 120 days.[2] The court ordered that the new effective date of the final rule is postponed to October 16, 2021. Pursuant to the court order, any obligation to comply with a deadline tied to the effective date is similarly postponed, and those obligations and deadlines are now tied to the postponed effective date.

To the extent that 5 U.S.C. 553 applies to this action, the Agency's implementation of this action without opportunity for public comment, effective immediately upon publication today in the **Federal Register**, is based on the good cause exception in 5 U.S.C. 553(b)(B). Seeking public comment is impracticable, unnecessary, and contrary to the public interest. The 120-day postponement of the effective date, until October 16, 2021, is required by court order in accordance with the court's authority to postpone a rule's effective date ''on such conditions as may be required and to the extent necessary to prevent irreparable injury'' pending judicial review (5 U.S.C. 705). Seeking prior public comment on this postponement would have been impracticable, as well as contrary to the public interest in the orderly issue and implementation of regulations.

Dated: May 22, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–11462 Filed 5–28–20; 8:45 am]

BILLING CODE 4164–01–P

[1] *R.J. Reynolds Tobacco Co. et al.* v. *United States Food and Drug Administration et al.,* No. 6:20–cv–00176 (E.D. Tex. filed April 3, 2020).

[2] *R.J. Reynolds Tobacco Co.,* No. 6:20–cv–00176 (E.D. Tex. May 8, 2020) (order granting joint motion and establishing schedule), Doc. No. 33.

DEPARTMENT OF STATE

22 CFR Part 161

[Public Notice: 11070]

RIN 1400–AF02

Environmental Protection: Regulations for Implementation of the National Environmental Policy Act (NEPA)

AGENCY: Department of State.

ACTION: Final rule with comments.

SUMMARY: The U.S. Department of State (Department) is issuing a final rule to update the Department's Regulations for Implementation of the National Environmental Policy Act (NEPA) to reflect a recent Executive Order that revised the process for the development and issuance of Presidential permits for certain facilities and land transportation crossings at the international boundaries of the United States.

DATES: This rule is effective July 13, 2020. Comments will be received until June 29, 2020.

ADDRESSES: Comments may be submitted at *https://www.regulations.gov* by searching for Docket Number DOS–2020–0013. Comments may also be submitted to M. Ross Alliston, NEPA Coordinator, at *AllistonMR@state.gov, or at* Office of Environmental Quality and Transboundary Issues, U.S. Department of State, 2201 C Street NW, Room 2726, Washington, DC 20520.

FOR FURTHER INFORMATION CONTACT: M. Ross Alliston, NEPA Coordinator, Office of Environmental Quality and Transboundary Issues, U.S. Department of State. 2201 C Street NW, Room 2726, Washington, DC 20520. (202) 647–4828, *AllistonMR@state.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

The President of the United States has authority to require permits for cross-border infrastructure based on his Constitutional powers over foreign affairs and national security vested by Article II of the Constitution. In Executive Orders 11423 and 13337, acting pursuant to the Constitution and the laws of the United States, including Section 301 of Title 3 of the United States Code, the President provided the Secretary of State the authority to receive applications for, and to issue or deny, Presidential permits for certain types of border facilities.

In 1968, under Executive Order 11423, President Lyndon B. Johnson designated and empowered the Secretary of State to receive applications and to issue permits for certain types of cross-border infrastructure. Executive Order 11423 also provided that, in the event of certain interagency disagreements, the President would make the final decision to issue or deny a permit. The types of infrastructure included: (i) Pipelines, conveyor belts, and similar facilities for the exportation or importation of petroleum, petroleum products, coal, minerals, or other products to or from a foreign country; (ii) facilities for the exportation or importation of water or sewage to or from a foreign country; (iii) monorails, aerial cable cars, aerial tramways and similar facilities for the transportation of persons or things, or both, to or from a foreign country; and (iv) bridges, to the extent that congressional authorization is not required.

In 2004, under Executive Order 13337, President George W. Bush revised the process to be followed by the Secretary of State in issuing Presidential permits for facilities for the exportation or importation of petroleum, petroleum products, coal, or other fuels while maintaining that, in the event of certain interagency disagreements, the President would make the final decision to issue or deny a permit. Because determinations regarding approval or denials of Presidential permits are Presidential actions, the requirements of NEPA, the National Historic Preservation Act of 1966, the Endangered Species Act of 1973, the Administrative Procedure Act, and other similar laws and regulations that do not apply to Presidential actions were inapplicable to such determinations, including determinations that were made by the Secretary of State or his delegate pursuant to Executive Order 11423 and 13337. However, as a matter of policy the Department of State conducted environmental reviews of Presidential permit applications consistent with NEPA in the course of preparing determinations pursuant to those Executive Orders.

On April 10, 2019, President Donald J. Trump issued Executive Order 13867,

entitled ''Issuance of Permits With Respect to Facilities and Land Transportation Crossings at the International Boundaries of the United States,'' 84 FR 15491, April 15, 2019, which revoked Executive Orders 11423 and 13337 and thus revoked the authority of the Secretary of State to issue or deny Presidential permits that had been granted by those Executive Orders. Section 1 of Executive Order 13867 provides that the purpose of the order is to promote cross-border infrastructure and facilitate the expeditious delivery of advice to the President regarding Presidential permitting decisions, which are an exercise of the President's foreign affairs authority. U.S. Constitution, Art. II, Sec. 2. While Section 3 of Executive Order 13867 leaves previously issued permits undisturbed, Section 2 of the Executive Order revises the procedures concerning applications for the issuance or amendment of Presidential permits for the construction, connection, operation, or maintenance of certain facilities at the international boundaries of the United States. Under the revised process, the Secretary of State receives applications and provides a recommendation to the President as to whether issuance or amendment of a permit would serve the foreign policy interests of the United States, but the Secretary does not make any decision to issue, deny, or amend a permit. The Secretary's recommendations are based on consultation with such other agency heads as the President may direct, as well as with domestic or foreign government officials as the President may deem necessary. Under Section 2(i) of Executive Order 13867, any decision to issue, deny, or amend a Presidential permit is made solely by the President. The President is not a ''federal agency'' to which NEPA applies (40 CFR 1508.12).

Section 2(j) of Executive Order 13867 instructed the Secretary of State, consistent with applicable law, to review the Department of State's regulations and to make any appropriate changes to them to ensure consistency with that Executive Order by May 29, 2020. Following such review, it has been determined that the Department's NEPA regulations at 22 CFR part 161 should be amended to reflect Executive Order 13867. In particular, the Department's NEPA regulations should be updated to remove all references to any permitting authority that has been revoked by Executive Order 13867.

II. Purpose of the Regulatory Action

This rulemaking fulfills the instruction in Executive Order 13867 that the Secretary of State review the Department of State's regulations and make any appropriate changes to them to ensure consistency with that Executive Order. This final rule updates 22 CFR part 161 to reflect the fact that the Secretary of State no longer has the authority to issue Presidential permits for cross-border infrastructure projects. The current regulations refer to authority previously exercised under Executive Orders 11423 and 13337 at §§ 161.7(c)(1) and 161.10. Because the authority referred to in these two places has been revoked, they are removed from Part 161.

Finally, since part 161 was last updated in 1980, this rule provides several nonsubstantive administrative updates.

III. Regulatory Analyses

Administrative Procedure Act (APA)

This rule is exempt from notice and comment rulemaking because it relates to a foreign affairs function of the United States. *See* 5 U.S.C. 553(a)(1). Specifically, the President's authority to grant or deny a border-crossing permit for international infrastructure is rooted in the President's inherent constitutional authority over foreign affairs as well as his authority as Commander-in-Chief. Presidents have exercised that inherent authority to authorize border crossing facilities since the Grant Administration. *See* Hackworth, *Digest of International Law,* Vol. IV, § 350 (1942).

In exercise of this constitutional foreign affairs authority, the President had authorized the Secretary of State, pursuant to Executive Orders 11423 and 13337, to receive applications and to issue or deny Presidential permits for certain types of cross-border facilities. Exercising the same authority, the President acted, in Executive Order 13867, to revoke the authority of the Secretary of State and to reserve to himself the cross-border permitting decisions described therein.

Notwithstanding the Department's determination that this rulemaking is exempt from notice and comment and without prejudice to this determination, the Department will accept public comment for 30 days after the date of publication.

Regulatory Flexibility Act

Because this final rule is exempt from the rulemaking provisions of 5 U.S.C. 553, it does not require analysis under the Regulatory Flexibility Act (RFA). Notwithstanding the inapplicability of the RFA, the Department has determined and hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities, given that the final rule has the potential to have an economic impact only on entities large enough to propose, finance, and construct cross-border infrastructure projects. Moreover, even if the final rule did have an economic impact on small entities, it would not affect a substantial number of them, because in no year has the Department ever received more than ten applications concerning cross-border infrastructure projects.

Unfunded Mandates Reform Act of 1995

This amendment does not involve a mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rulemaking has been found not to be a major rule within the meaning of the Small Business Regulatory Enforcement Fairness Act of 1996.

Executive Orders 12866 and 13563, Regulatory Planning

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, distributed impacts, and equity). The Department believes that the benefits of this rulemaking outweigh any cost to the public, which is anticipated to be minimal. This rule has been designated as a significant rulemaking under Executive Order 12866.

Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs

This rule is not subject to the requirements of E.O. 13771 because this rule results in no more than *de minimis* costs.

Executive Order 12988, Civil Justice Reform

The Department of State reviewed this rulemaking in light of sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal

standards, and reduce burden. No retroactive effect will be given to this rule, and no administrative appeal procedures must be exhausted before an action against the Department may be initiated.

Executive Order 12372, Intergovernmental Review of Federal Programs

This rule is not subject to Executive Order 12372. This rule updates the Department's NEPA regulations and does not implicate provision of non-Federal funds by State and local governments. Similarly, the Department's NEPA regulations do not implicate Federal financial assistance or direct Federal development within the scope of Executive Order 12372.

National Environmental Policy Act

In this final rule, the Department proposes to implement the Presidential directive in Section 2(j) of Executive Order 13867 to bring the Department of State's regulations into conformity with Executive Order 13867. The Council on Environmental Quality (CEQ) does not direct agencies to prepare a NEPA analysis before establishing agency NEPA procedures as required by the CEQ regulations for implementing the procedural provisions of NEPA pursuant to 40 CFR 1505.1 and 1507.3. The determination that establishing agency NEPA procedures does not require NEPA analysis and documentation has been upheld in *Heartwood, Inc.* v. *U.S. Forest Service,* 73 F. Supp. 2d 962, 972–73 (S.D. Ill. 1999), aff'd, 230 F. 3d 947, 954–55 (7th Cir. 2000). Moreover, the Department of State has no discretion to deviate from the presidential instructions set forth in Executive Order 13867, and nondiscretionary actions are not subject to NEPA analytical requirements. *Department of Transportation* v. *Public Citizen,* 541 U.S. 752, 756, 770 (2004).

Executive Order 13132, Federalism

The policies contained in this final rule do not have any substantial direct effect on 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. Nor does this final rule impose substantial direct compliance costs on state and local governments. Therefore, consultation with the states is not required.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

The Department has determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not preempt tribal law. Accordingly, Executive Order 13175 does not apply to this rulemaking.

Paperwork Reduction Act

The Department has determined that this rulemaking does not create or revise any information collection that would require approval under the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35).

List of Subjects in 22 CFR Part 161

Environmental impact statements.

Accordingly, for the reasons set forth above, title 22, chapter I, subtitle Q, part 161 is amended as follows:

PART 161—REGULATIONS FOR IMPLEMENTATION OF THE NATIONAL ENVIRONMENTAL POLICY ACT (NEPA)

■ 1. The authority citation for part 161 is revised to read as follows:

Authority: 22 U.S.C. 2651a and 2656; 42 U.S.C. 4321 *et seq.;* E.O. 11514, 34 FR 4247, 3 CFR, 1966–1970, Comp., p. 902, as amended by E.O. 11991, 42 FR 26927, 3 CFR, 1977 Comp., p. 123; E.O. 13867, 84 FR 15491.

■ 2. In part 161, remove the words ''Office of Environment and Health'' and add in their place the words ''Office of Environmental Quality and Transboundary Issues'' wherever they occur.

§ 161.6 [Amended]

■ 3. Amend § 161.6in paragraph (a)(2) introductory text by removing the words ''Congressional Relations'' and adding in their place the words ''Legislative Affairs''.

§ 161.7 [Amended]

■ 4. Amend § 161.7 by removing and reserving paragraph (c)(1).

§ 161.10 [Removed and Reserved]

■ 5. Remove and reserve § 161.10.

Zachary A. Parker,

Director, Office of Directives Management, U.S. Department of State.

[FR Doc. 2020–10991 Filed 5–28–20; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 339

[Docket ID: DoD–2020–OS–0019]

RIN 0790–AK97

DoD Guidance Documents

AGENCY: Office of the Secretary of Defense, DoD.

ACTION: Final rule.

SUMMARY: This final rule sets forth the Department of Defense's (DoD) policies and processes governing the issuance and use of guidance documents. By issuing this final rule, DoD also responds to the Executive Order titled: ''Promoting the Rule of Law Through Improved Agency Guidance Documents,'' which requires federal agencies to finalize regulations, or amend existing regulations as necessary, to set forth processes and procedures for issuing guidance documents.

DATES: *Effective Date:* This final rule is effective May 29, 2020.

FOR FURTHER INFORMATION CONTACT: Patricia Toppings, 571–372–0485.

SUPPLEMENTARY INFORMATION: This final rule codifies the Department's policies and procedures regarding guidance documents. The policies and procedures in this final rule apply to all non-exempt DoD guidance documents, which DoD defines in § 339.1. These procedures require all DoD guidance documents to receive appropriate coordination and review. Before guidance documents are issued, they must be reviewed to ensure they are written in plain language and do not impose any substantive legal requirements on the public above and beyond statute or regulation. All guidance documents must include a clear and prominent statement effectively stating that the contents of the guidance document do not have the force and effect of law and are not meant to bind the public in any way, and the guidance document is intended only to provide clarity to the public regarding existing requirements under the law or agency regulations. Recognizing the fact that, even though guidance documents are not legally binding, they could nevertheless have a substantial economic impact on regulated entities that alter their conduct to conform to the guidance, this final rule requires a good faith assessment of the cost impact on the public of the guidance document.

This final rule also incorporates other policies and procedures, such as

describing when guidance documents are subject to notice and an opportunity for public comment and how they will be made available to the public after issuance. These procedures are intended to ensure that the public has a fair and sufficient opportunity to comment on guidance documents when appropriate and practicable and has access to guidance documents issued by the Department. The final rule also provides a process for interested parties to petition the Department for the withdrawal or modification of guidance documents.

Administrative Procedure

Under the Administrative Procedure Act, an agency may waive the normal notice and comment procedures if the action is a rule of agency organization, procedure, or practice. See 5 U.S.C. 553(b)(3)(A). Since this final rule merely incorporates procedures applicable to the Department's administrative procedures into the Code of Federal Regulations, notice and comment are not necessary.

Rulemaking Analyses

Executive Order 12866, ''*Regulatory Planning and Review*'' *and Executive Order 13563,* ''*Improving Regulation and Regulatory Review*''

This rulemaking is not a significant regulatory action under Executive Order 12866. The Department does not anticipate that this rulemaking will have an economic impact on regulated entities. This is a rule of agency procedure and practice. The final rule describes the Department's internal policies and procedures for its guidance documents. The Department has adopted these internal policies and procedures as part of its regulatory reform initiative, and has not incurred any additional resource costs in doing so. Regulated entities and the public will benefit from these policies and procedures through increased agency deliberations and more opportunities to comment on guidance documents.

Executive Order 13771, ''*Reducing Regulation and Controlling Regulatory Costs*''

This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

Public Law 96–354, ''*Regulatory Flexibility Act*'' *(5 U.S.C. 601)*

Since notice and comment rulemaking is not necessary for this rule, the provisions of the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601–612) do not apply.

Executive Order 13132, ''*Federalism*''

Executive Order 13132 requires agencies to ensure meaningful and timely input by State and local officials in the development of regulatory policies that may have 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. This action has been analyzed in accordance with the principles and criteria contained in Executive Order 13132, and it has been determined that this action will not have a substantial direct effect or federalism implications on the States and would not preempt any State law or regulation or affect the States' ability to discharge traditional State governmental functions. Therefore, consultation with the States is not necessary.

Executive Order 13175, ''*Consultation and Coordination With Indian Tribal Governments*''

This final rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13175. Because this rulemaking does not significantly or uniquely affect the communities of the Indian tribal governments or impose substantial direct compliance costs on them, the funding and consultation requirements of Executive Order 13175 do not apply.

Public Law 96–511, ''*Paperwork Reduction Act*'' *(44 U.S.C. Chapter 35)*

The Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*) requires that DoD consider the impact of paperwork and other information collection burdens imposed on the public and, under the provisions of PRA section 3507(d), obtain approval from the Office of Management and Budget for each collection of information it conducts, sponsors, or requires through regulations. It has been determined there are no new information collection requirements associated with this final rule.

Section 202, Public Law 104–4, ''*Unfunded Mandates Reform Act*''

It has been determined that this final rule does not contain a Federal mandate that may result in expenditure by State, local and tribal governments, in aggregate, or by the private sector, of $100 million or more in any one year.

List of Subjects in 32 CFR Part 339

Administrative practice and procedure, Guidance documents.

■ In consideration of the foregoing, the Office of the Secretary of Defense adds 32 CFR part 339 to read as follows:

PART 339—DOD GUIDANCE DOCUMENTS

Sec.

339.1 General.
339.2 Initial review process.
339.3 Good faith cost estimates.
339.4 Departmental review and submission to OIRA.
339.5 Designation procedures.
339.6 Non-significant guidance documents.
339.7 Significant guidance document.
339.8 Notice-and-comment procedures.
339.9 Public access to effective guidance documents.
339.10 Petitions for guidance.
339.11 Rescinded guidance.
339.12 Exigent circumstances.
339.13 Reports to Congress and GAO.
339.14 Use of guidance documents.

Authority: 5 U.S.C. 552a.

§ 339.1 General.

(a) This part provides policies and procedures governing all phases of issuing, modifying, or rescinding guidance documents within DoD.

(b) Subject to the qualifications and exemptions contained in this part, these policies and procedures apply to all guidance documents intended to have future effect on the behavior of regulated parties issued by all components of the Department, including regional and district offices.

(c) For purposes of this part, the term *guidance document* includes any statement of agency policy or interpretation concerning a statute, regulation, or technical matter within the jurisdiction of the Department that is intended to have general applicability and future effect on the behavior of regulated parties, but which is not intended to have the force or effect of law in its own right and is not otherwise required by statute to satisfy the rulemaking procedures specified in 5 U.S.C. 553 or 5 U.S.C. 556. The term is not confined to formal written documents; guidance may come in a variety of forms, including, but not limited to, letters, memoranda, circulars, bulletins, advisories, and may include video, audio, and Web-based formats. See OMB Memorandum M–20–02, ''Guidance Implementing Executive Order 13891, Titled ''Promoting the Rule of Law Through Improved Agency Guidance Documents,'' '' dated October 31, 2019.

(d) This part does not apply to:

(1) Agency statements of specific applicability, including advisory or legal opinions directed to particular parties about circumstance-specific questions (*e.g.,* case or investigatory

letters responding to complaints, warning letters), notices regarding particular locations or facilities (*e.g.,* guidance pertaining to the use, operation, or control of a government facility or property), and correspondence with individual persons or entities (*e.g.,* congressional correspondence), except documents ostensibly directed to a particular party but designed to guide the conduct of the broader regulated public;

(2) Agency statements that do not set forth a policy on a statutory, regulatory, or technical issue or an interpretation of a statute or regulation, including speeches and individual presentations, editorials, media interviews, press materials, or congressional testimony that do not set forth for the first time a new regulatory policy;

(3) Rules promulgated pursuant to notice and comment under 5 U.S.C. 553, or similar statutory provisions;

(4) Rules exempt from rulemaking requirements under 5 U.S.C. 553(a);

(5) Rules of agency organization, procedure, or practice;

(6) Decisions of agency adjudications under 5 U.S.C. 554, or similar statutory provisions;

(7) Internal guidance directed solely to the issuing agency or other agencies (or personnel of such agencies) that is not intended to have substantial future effect on the behavior of regulated parties or the public;

(8) Internal guidance that is made public only because release is required under the Freedom of Information Act or agency disclosure policies;

(9) Legal briefs, other court filings, or positions taken in litigation or enforcement actions;

(10) Legal opinions by the Office of Legal Counsel at the Department of Justice.

(11) Internal executive branch legal advice or legal advisory opinions addressed to executive branch officials;

(12) Guidance pertaining to military or foreign affairs functions, or to a national security or homeland security function of the United States (other than guidance documents involving procurement or the import or export of non-defense articles and services);

(13) Grant solicitations and awards; or

(14) Contract solicitations and awards.

§ 339.2 Initial review process.

(a) Prior to submitting guidance documents for departmental review, Components seeking to issue, modify, or rescind a guidance document should submit a draft copy of that document, along with the component's designation request (see § 339.5 of this part) and good faith cost estimate (see § 339.3 of this part), to their Federal Register Liaison Officer.

(b) Before such a guidance document can be cleared for departmental review, the appropriate DoD or OSD Federal Register Liaison Officer will review it to ensure that it satisfies the following requirements:

(1) For significant guidance (see § 339.7 of this part), **Federal Register** required formatting.

(2) The guidance document complies with all relevant statutes and regulations (including any statutory deadlines for agency action);

(3) The guidance document identifies or includes:

(i) The term ''guidance'' or its functional equivalent;

(ii) The issuing component of the Department;

(iii) A unique identifier, including, at a minimum, the date of issuance and title of the document and its Z–RIN (a regulation identifier number), if applicable;

(iv) The activity or entities to which the guidance applies;

(v) Citations to applicable statutes and regulations;

(vi) A statement noting whether the guidance is intended to revise or replace any previously issued guidance and, if so, sufficient information to identify the previously issued guidance; and

(vii) A short summary of the subject matter covered in the guidance document at the top of the document.

(4) The guidance document avoids using mandatory language, such as ''shall,'' ''must,'' ''required,'' or ''requirement,'' unless the language is describing an established statutory or regulatory requirement or is addressed to DoD staff and will not foreclose the Department's consideration of positions advanced by affected private parties or is intended to have a substantial future effect on the behavior of regulated parties;

(5) The guidance document is written in plain and understandable English;

(6) All guidance documents include the following disclaimer prominently: ''The contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or departmental policies.''

§ 339.3 Good faith cost estimates.

Even though not legally binding, some agency guidance may result in a substantial economic impact. For example, the issuance of departmental guidance may induce private parties to alter their conduct to conform to recommended standards or practices, thereby incurring costs beyond the costs of complying with existing statutes and regulations. While it may be difficult to predict with precision the economic impact of voluntary guidance, the proposing component of the Department must, to the extent practicable, make a good faith effort to estimate the likely economic cost impact of the guidance document to determine whether the document might be significant. When the component is assessing or explaining whether it believes a guidance document is significant, it will, at a minimum, provide the same level of analysis that would be required for a major determination under the Congressional Review Act (5 U.S.C. chapter 8). When it is determined that a guidance document will be economically significant (see § 339.7(a)(1) of this part), the component must conduct and publish a Regulatory Impact Analysis of the sort that would accompany an economically significant rulemaking (see requirements in E.O. 12866, E.O. 13563, and OMB Circular A–4), to the extent reasonably possible.

§ 339.4 Departmental review and submission to OIRA.

(a) After the appropriate FRLO completes his or her initial review, a guidance document will be internally coordinated within the proposing component and formally coordinated throughout the Department with other components who have equities. Mandatory coordinators on all guidance documents are the Chief Management Officer, Department of Defense and the component's General Counsel.

(b) The proposing component will adjudicate DoD and OSD Component comments and return a final guidance document package to the appropriate DoD or OSD Federal Register Liaison Officer for submission to the Office of Management and Budget (OMB), Office of Information and Regulations Affairs (OIRA) for a significance determination.

(c) Guidance documents deemed by OIRA to be ''significant'' (see § 339.7 of this part) must be reviewed and approved by the Department's Regulatory Policy Officer before OIRA formally reviews them.

§ 339.5 Designation procedures.

(a) The proposing component will prepare a designation request for guidance documents. Designation requests must include the following information:

(1) A summary of the guidance document; and

(2) The component's recommended designation of ''not significant,''

''significant,'' or ''economically significant,'' as well as a justification for that designation.

(b) The appropriate DoD or OSD Federal Register Liaison Officer will seek a significance determination from OIRA for guidance documents in the same manner as for rulemakings. OIRA review will occur prior to the publishing of guidance documents, and with sufficient time to allow OIRA to review the designation request and the guidance document to determine if it meets the definition of ''significant'' or ''economically significant'' under Executive Order 13891.

(c) Prior to being published, guidance documents determined to be ''significant'' or ''economically significant'' are subject to formal review and interagency coordination by OIRA. The OIRA review, to include interagency coordination, is to be consistent with Executive Order 12866.

(d) Significant guidance documents (see § 339.7 of this part) must be reviewed and approved by the Department's Regulatory Policy Officer before OIRA formally reviews them.

(e) Once the OMB/OIRA has cleared a guidance document for publication, the appropriate DoD or OSD Federal Register Liaison Officer will coordinate the guidance document with the Defense Office of Prepublication and Security Review (DOPSR). The FRLO will notify the component of DOPSR's approval and that the guidance document can be approved for **Federal Register** publication or signed for placement on the central website.

§ 339.6 Non-significant guidance documents.

(a) If the guidance document is determined to be non-significant within the meaning of § 339.7 of this part, the appropriate DoD or OSD Federal Register Liaison Officer will advise the proposing component to proceed with issuance of the guidance.

(b) For each such guidance document, the proposing component should forward it to the appropriate authority for approval. OSD PSAs or equivalents can delegate in writing the authority to approve non-significant guidance documents to subordinate officials at or above the level of a General/Flag Officer, Senior Executive Service member, or equivalent. The proposing component should include a statement in the action memorandum to the approving authority that the guidance document has been reviewed and cleared as non-significant by OIRA.

(c) After the approving authority signs the non-significant guidance document, it should be forwarded to the DoD Regulatory Program staff for publication on the department's guidance document website located at *https://open.defense.gov/Regulatory-Program/Guidance-Documents/*.

§ 339.7 Significant guidance documents.

(a) The term ''significant guidance document'' means a guidance document that will be disseminated to regulated entities or the general public and that may reasonably be anticipated:

(1) To lead to an annual effect on the economy of $100 million or more or adversely affect in a material way the U.S. economy, a sector of the U.S. economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (a guidance document is economically significant if it meets the criteria in this paragraph);

(2) To create serious inconsistency or otherwise interfere with an action taken or planned by another Federal agency;

(3) To alter materially the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) To raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in E.O. 12866, as further amended.

(b) The term ''significant guidance document'' does not include the categories of documents excluded by § 339.1(d) or any other category of guidance documents exempted in writing in consultation with OIRA.

(c) Significant guidance documents, to include economically significant guidance documents, must be reviewed by OIRA under E.O. 12866 before issuance; and must demonstrate compliance with the applicable requirements for regulations or rules, including significant regulatory actions, set forth in E.O. 12866, E.O. 13563, E.O. 13609, E.O. 13771, and E.O. 13777.

(d) Each proposed DoD guidance document determined by OIRA to be significant must be approved by an OSD Principal Staff Assistant or equivalent appointed by the President.

(e) Significant guidance documents have to be published for notice and comment in accordance with § 339.8 of this part before they can be issued.

§ 339.8 Notice-and-comment procedures.

(a) Except as provided in paragraph (b) of this section, all proposed DoD guidance documents determined to be a ''significant guidance document'' within the meaning of § 339.7 shall be subject to the following notice and comment procedures. After receiving clearance from OIRA to publish a proposed significant guidance document, the proposing component shall publish a notice in the **Federal Register** announcing that a draft of the proposed guidance document is publicly available on *Regulations.gov,* shall invite public comment on the draft document for a minimum of 30 days. After the comment period ends, the proposing component shall prepare and post a public response to major concerns raised in the comments, as appropriate, in the docket on *Regulations.gov*. Then the component will prepare a final notice that will be coordinated within the department and submitted to OIRA for review, interagency coordination, and clearance for publishing in the **Federal Register**. Both the proposed and final notices shall be approved by the DoD RPO before OIRA review, and by an OSD Principal Staff Assistant or equivalent appointed by the President after OIRA clearance and DOPSR approval.

(b) The notice and comment requirements of paragraph (a) of this section will not apply to any significant guidance document or categories of significant guidance documents for which the proposing component finds, in consultation with their component OGC and OIRA, good cause that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest (and incorporates the finding of good cause and a brief statement of reasons therefor in the guidance issued).

§ 339.9 Public access to effective guidance documents.

(a) The DoD Regulatory Policy Team shall:

(1) Ensure all final guidance documents in effect are identified by a unique identifier which includes, at a minimum, the document's title and date of issuance or revision and its Z–RIN, if applicable, are published and maintained on a central website located at *https://open.defense.gov/Regulatory-Program/Guidance-Documents/* in a single, searchable, indexed database, and available to the public;

(2) Note on its website that guidance documents do not bind the public, except as authorized by law or as incorporated into a contract;

(3) Announce on its website a means for the public to comment electronically on any guidance documents that are subject to the notice and comment procedures; and

(4) Receive complaints from the public that a component of the Department is not following the requirements of OMB's Memorandum

M–20–02, ''Guidance Implementing Executive Order 13891, Titled ''Promoting the Rule of Law Through Improved Agency Guidance Documents'','' dated October 31, 2019, or is improperly treating a guidance document as a binding requirement.

(b) Each component responsible for issuing guidance documents shall:

(1) Submit final guidance documents to the DoD Regulatory Policy Team at the email address *osd.mc-alex.ocmo.mbx.guidance-documents@mail.mil* for posting to the Department's central website.

(2) Address complaints from the public that they are not following the requirements of OMB's Memorandum M–20–02, ''Guidance Implementing Executive Order 13891, Titled ''Promoting the Rule of Law Through Improved Agency Guidance Documents'','' dated October 31, 2019, or are improperly treating a guidance document as a binding requirement.

§ 339.10 Petitions for guidance.

(a) Any person may petition the Department to withdraw or modify a particular guidance document by sending a written request to the DoD Regulatory Program staff at email address *osd.mc-alex.ocmo.mbx.guidance-documents@mail.mil*. Please use the words ''GUIDANCE: [Insert the title of the guidance document]'' in the subject line of the email message. The DoD Regulatory Program staff will provide the request to the issuing component of the guidance document for response.

(b) The issuing component should respond to all requests within 90 days after receipt of the request, or as timely as possible given any constraints of the request. For recordkeeping purposes, the issuing component will provide a copy of their response to the DoD Regulatory Program staff at email address *osd.mc-alex.ocmo.mbx.guidance-documents@mail.mil*.

§ 339.11 Rescinded guidance.

(a) All effective guidance documents must appear on the central website. If the guidance document does not appear on the central website, the guidance is rescinded and without effect.

(b) No component may cite, use, or rely on guidance documents that are rescinded, except to establish historical facts.

§ 339.12 Exigent circumstances.

In emergency situations or when the proposing component is required by statutory deadline, court order, or executive order to act more quickly than normal review procedures allow, the proposing component shall coordinate with OGC and the appropriate DoD or OSD Federal Register Liaison Officer to notify OIRA as soon as possible and, to the extent practicable, shall comply with the requirements of this part at the earliest opportunity.

§ 339.13 Reports to Congress and GAO.

Upon the issuance of a final guidance document, the appropriate Federal Register Liaison Officer will submit a report to Congress and GAO in accordance with the procedures described in 5 U.S.C. 801 (the ''Congressional Review Act''). If the CRA procedures are not followed, the guidance document can be nullified.

§ 339.14 Use of guidance documents.

Guidance documents cannot create binding requirements that do not already exist by statute or regulation. Accordingly, noncompliance with guidance documents cannot be used as a basis for proving violations of applicable law. Guidance documents can do no more, with respect to prohibition of conduct, than articulate the Department's understanding of how a statute or regulation applies to particular circumstances.

Dated: May 26, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–11551 Filed 5–28–20; 8:45 am]

BILLING CODE 5001–06–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2007–0113; FRL–10009–10-Region 4]

Air Plan Approval; Georgia: Definition for Permitting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a portion of a State Implementation Plan (SIP) revision submitted by the State of Georgia, through the Georgia Department of Natural Resources' Environmental Protection Division (GA EPD) on September 19, 2006, with a clarification submitted on November 6, 2006, and a supplemental submittal transmitted on November 27, 2019. EPA is approving portions of a definition that impacts existing minor new source review (NSR) permitting regulations because the State has demonstrated it is consistent with the Clean Air Act (CAA or Act).

DATES: This rule is effective June 29, 2020.

ADDRESSES: EPA has established a docket for this action under Docket Identification No. EPA–R04–OAR–2007–0113. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information may not be publicly available, *i.e.,* Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the 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. EPA requests that if at all possible, you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: D. Brad Akers, 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. Mr. Akers can also be reached via telephone at (404) 562–9089 or via electronic mail at *akers.brad@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. What action is EPA finalizing?

EPA is approving certain changes to the Georgia SIP that were provided to EPA by GA EPD via a letter dated September 19, 2006. EPA previously approved the majority of the changes to Georgia rules originally included in the September 19, 2006, submittal.[1] In addition, GA EPD has withdrawn several portions of the SIP revision from

[1] EPA approved portions of the September 19, 2006, SIP revision as follows: Changes to Rule 391–3–1–.01, *Definitions,* were approved on February 9, 2010 (75 FR 6309); changes to Rule 391–3–1–.02, *Provisions,* were approved on February 9, 2010 (75 FR 6309), December 1, 2010 (75 FR 74642), and September 1, 2015 (80 FR 52627); and changes to Rule 391–3–1–.03, *Permits,* were approved on April 9, 2013 (78 FR 21065) and November 22, 2019 (84 FR 64427).

EPA consideration.[2] In this action, EPA is approving the portion of this SIP revision that makes changes to the State's Rule 391–3–1–.01, *Definitions*. The portion of the SIP revision considered adds a definition for ''Pollution control project'' (PCP)—which GA EPD describes as environmentally-beneficial projects that reduce criteria pollutant emissions—that relates to minor NSR applicability for construction permitting under Rule 391–3–1–.03, *Permits*. The changes to this rule and EPA's rationale for approval are described in more detail in EPA's notice of proposed rulemaking (NPRM) published on March 16, 2020. *See* 85 FR 14843.

Comments on EPA's March 16, 2020, NPRM were due on April 15, 2020. EPA received comments which, as discussed in Section III below, do not challenge the underlying rationale for EPA's proposed action. Accordingly, EPA is finalizing action on the March 16, 2020, NPRM.

II. EPA's Analysis of the Georgia's Submittal

EPA is approving portions of the definition of ''Pollution control project'' into the Georgia SIP at Rule 391–3–1–.01(qqqq). This definition lists certain projects, described as ''environmentally beneficial,'' that are exempted from the minor NSR[3] construction permit requirements pursuant to Rule 391–3–1–.03(6)(j). The exemption does not apply to sources subject to major NSR requirements under either 391–3–1–.02(7) (''Prevention of Significant Deterioration [PSD] of Air Quality''), or 391–3–1–.03(8) ''Permit Requirements'' under paragraph (c), (Georgia's nonattainment new source review (NNSR) program). The exemption for PCPs applies to minor sources only, limiting any emissions increases from the exempted projects to below the major source thresholds for all pollutants.

EPA previously approved the exemption for PCPs for minor sources at .03(6)(j) on February 9, 2010 (75 FR 6309) but did not act on the PCP definition at Rule 391–3–1–.01(qqqq) at that time. In this action, EPA is approving a definition of ''Pollution control project'' at .01(qqqq). Because this definition only applies to minor sources, it is not impacted by the United States Court of Appeals for the District of Columbia Circuit decision in *New York* v. *EPA,* 413 F.3d 3 (D.C. Cir.), in which the D.C. Circuit vacated an exemption for PCPs from the federal NSR regulations for major sources. Georgia's previously approved NSR regulations governing major sources are consistent with federal requirements and the D.C. Circuit decision on PCPs for major NSR.

On June 29, 2017 (82 FR 29469), EPA published a NPRM proposing approval of changes to 391–3–1–.01, *Definitions,* and 391–3–1–.03, *Permits,* and published an accompanying direct final rule. *See* 82 FR 29418. EPA specifically proposed to approve a definition of ''Pollution control project'' at 391–3–1–.01(qqqq), which included subparagraphs .01(qqqq)1. through 8., as a clarifying amendment to an existing exemption from minor NSR permitting at 391–3–1–.03(6)(j). The proposed rule stated that if EPA received adverse comment on the direct final rule, then the Agency would withdraw the direct final rule and address public comments received in a subsequent final rule based on the proposed rule. EPA received one adverse comment regarding the portion of the direct final rule revising 391–3–1–.01, *Definitions,* and EPA accordingly withdrew the direct final rule on August 22, 2017.[4] *See* 82 FR 39671.

Since the August 22, 2017, withdrawal of EPA's direct final rule, GA EPD has withdrawn several portions of the definition at .01(qqqq) from EPA consideration. Specifically, on November 27, 2019, GA EPD withdrew .01(qqqq)1. and .01(qqqq)3. through 8., and submitted a supplemental justification for the approval of .01(qqqq)2. into the SIP.[5] The remaining list of projects EPA is considering in this action at .01(qqqq)2. are as follows: ''[e]lectrostatic precipitators, baghouses, high-efficiency multiclones, or scrubbers for control of particulate matter or other air contaminants.'' EPA proposed to approve this remaining portion of the definition on March 16, 2020. *See* 85 FR 14843.

EPA is approving the remaining portion of the definition, specifically the introductory paragraph and subparagraph .01(qqqq)2. EPA has evaluated the exemption and believes, in its technical judgment, that the listed projects will reduce emissions of both NAAQS and non-NAAQS pollutants. Additionally, EPA notes that these projects will not lead to collateral emissions increases of any NAAQS pollutants. As a result, these types of projects already qualify for Georgia's preexisting minor NSR exemption at Rule 391–3–1–.03(6)(i)3. That provision exempts projects that fall below certain specified emissions thresholds. Since the projects included under Rule 391–3–1–.01(qqqq)2. will not increase emissions of any NAAQS pollutant, they would previously have been exempted under those thresholds. Therefore, the revision will not interfere with any applicable requirement concerning attainment and reasonable further progress (as defined in CAA section 171), or any other applicable requirement of the CAA, consistent with CAA section 110(l). EPA believes that these projects are otherwise appropriately exempted from Georgia's minor NSR program under CAA section 110(a)(2)(C). That provision requires a program within the State to regulate the construction and modification of sources such that the NAAQS are maintained. By definition, a project that will not lead to any emissions increases will not negatively impact the NAAQS.

To the extent CAA section 193 applies to this action, EPA has concluded that the revision is consistent with the requirements of that provision because these changes will not lead to any increases of NAAQS pollutants. *See* EPA's March 16, 2020, NPRM (85 FR 14843) for more detail on EPA's rationale for approval.

III. Response to Comments

EPA received two comments that do not directly address the March 16, 2020, NPRM. EPA also received one comment that generally supports the proposed action, but raises other points that are summarized and discussed below.

Comment 1: The Commenter requests that EPA adequately publicize that Georgia Rule 391–3–1.01(qqqq)1. and (qqqq)3. through 8.—which GA EPD withdrew from EPA consideration—are not part of the SIP. Specifically, the Commenter requests that EPA include

[2] GA EPD withdrew portions of the September 19, 2006, SIP revision as follows: 391–3–1–.02 on January 25, 2016 and portions of 391–3–1–.01 on November 27, 2019.

[3] EPA's regulations governing the implementation of NSR permitting programs are contained in 40 CFR 51.160–51.166; 52.21, 52.24; and part 51, Appendix S. The CAA NSR program is composed of three separate programs: PSD, NNSR, and Minor NSR. PSD is established in part C of title I of the CAA and applies to major stationary sources in areas that meet the national ambient air quality standards (NAAQS)—''attainment areas''—as well as areas where there is insufficient information to determine if the area meets the NAAQS—''unclassifiable areas.'' The NNSR program is established in part D of title I of the CAA and applies to major stationary sources in areas that are not in attainment of the NAAQS—''nonattainment areas.'' The Minor NSR program applies to stationary sources that do not require PSD or NNSR permits. Together, these programs are referred to as the NSR programs.

[4] The adverse comment received on the June 29, 2017, proposed rule is included in the docket for this action.

[5] The November 27, 2019, partial withdrawal letter and accompanying Attachment A transmitting supporting documentation for the remainder of the SIP revision are included in the docket for this action.

an explanation at 40 CFR 52.570(c), ''EPA Approved Georgia Regulations,'' confirming that these provisions are not included in the SIP and that this explanation remain in place as long as these provisions remain in the State's regulations.

Response 1: The Commenter does not challenge the substance of the State rule EPA has proposed to approve into Georgia's SIP. Consistent with its current practice, EPA Region 4 will identify exceptions from the SIP-approved version of Rule 391–3–1–.01 in the explanations column of the Georgia SIP table at § 52.570(c), and the explanation will remain in place until the need for the explanation is eliminated through an approved SIP revision.

Comment 2: The Commenter requests that EPA include the aforementioned explanation on EPA Region 4's website titled ''EPA Approved Statutes and Regulations in the Georgia SIP'' [6] and notes that exceptions at Rule 391–3–1–.01 listed at 40 CFR 52.570(c) are not reproduced on the website. The Commenter states that it is essential that EPA's website correctly identify the approved State regulations to ensure that the public is adequately informed of the operative provisions of the Georgia SIP.

Response 2: These comments regarding Region 4's website are outside the scope of this action. However, EPA acknowledges that the Region 4 website may have created confusion. The website titled ''Approved Air Quality Implementation Plans in Georgia'' contains the following statement:

About this website: The official SIPs, TIPs, and FIPs are contained in regulations promulgated in the **Federal Register** and codified in the U.S. Code of Federal Regulations (CFR). EPA's web-versions of the approved SIPs, TIPs, and FIPs are for reference. While we make every effort to maintain the accuracy of the files accessible here, inconsistencies may occur. Please contact us using the link below if you find any errors in these files.

To add clarity, EPA Region 4 has revised this statement as follows and placed it on all three of its websites related to Georgia's SIP: [7]

About this website: This website does not necessarily represent the current version of the SIPs, TIPs, or FIPs. The official SIPs, TIPs, and FIPs are contained in regulations promulgated in the **Federal Register** and codified in the U.S. Code of Federal Regulations (CFR). While we make every effort to maintain the accuracy of the files accessible here, inconsistencies may occur. Please contact us using the link below if you find any errors in these files.

Comment 3: The Commenter urges EPA to ensure that Georgia implements its SIP and not allow the State to apply the exemptions at 391–3–1–.01(qqqq)1. and (qqqq)3. through 8 to minor NSR. The Commenter states that it has experience with the State implementing State regulations that differ from the SIP and provides information related to the issuance of an air permit as an example.

Response 3: EPA agrees that it retains oversight authority to ensure that states are adequately implementing SIP-approved rules. Should EPA discover evidence to support a determination that GA EPD is misapplying the exemptions approved through this action, the Agency retains oversight authority to remedy this issue, such as through a failure to implement action. EPA appreciates the Commenter's specific information regarding a GA EPD permitting action. However, the Commenter's statements related to this unrelated permitting action are outside the scope of this action.

IV. Incorporation by Reference

In this document, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of the Georgia Rule 391–3–1–.01, entitled ''Definitions,'' effective July 23, 2018 which adds a definition for a ''Pollution control project.'' [8] [9] 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 INFORMATION CONTACT** section of this preamble for more information). Therefore, these materials have been approved by EPA for inclusion in the State implementation plan, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[10]

V. Final Action

EPA is approving the portion of the September 19, 2006, SIP revision that adds a definition at Rule 391–3–1–.01(qqqq). EPA believes this change is consistent with the CAA and will not impact the NAAQS or interfere with any other applicable requirement of the Act.

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 action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this 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);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- 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);

[6] This website is located at *https://www.epa.gov/sips-ga/epa-approved-statutes-and-regulations-georgia-sip*. It is a sub-site of the website titled ''Approved Air Quality Implementation Plans in Georgia,'' located at *https://www.epa.gov/sips-ga,* which is a sub-site of the website titled ''Approved Air Quality Implementation Plans in Region 4,'' located at *https://www.epa.gov/air-quality-implementation-plans/approved-air-quality-implementation-plans-region-4.*

[7] See footnote 6.

[8] The effective date of the change to Rule 391–3–1–.01 made in Georgia's September 19, 2006, SIP revision is July 13, 2006. However, for purposes of the state effective date included at 40 CFR 52.570(c), that change to Georgia's rule is captured and superseded by Georgia's update in a July 31, 2018, SIP revision, state effective on July 23, 2018, which EPA previously approved on November 22, 2019. *See* 84 FR 64427.

[9] Except for (qqqq)1. and (qqqq)3. through 8., which were withdrawn from EPA consideration on November 27, 2019.

[10] *See* 62 FR 27968 (May 22, 1997).

• 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).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 28, 2020. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. *See* section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides, Volatile organic compounds.

Mary Walker,

Regional Administrator, Region 4.

Accordingly, 40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart L—Georgia

■ 2. Section 52.570(c) is amended by revising the entry for ''391–3–1–.01'' to read as follows:

§ 52.570 Identification of plan.

* * * * *

(c) * * *

EPA Approved Georgia Regulations

State citation	Title/subject	State effective date	EPA approval date	Explanation
391–3–1–.01	Definitions	7/23/2018	5/29/2020, [Insert citation of publication].	Except the first paragraph, sections (a)–(nn), (pp)–(ccc), (eee)–(jjj), (nnn)–(bbbb), (dddd)–(mmmm), (rrrr)–(ssss), approved on 12/4/2018 with a State-effective date of 7/20/2017; sections (ddd) and (cccc)—approved on 2/2/1996 with a State-effective date of 11/20/1994; (nnnn), approved on 1/5/2017 with a State-effective date of 8/14/2016; and sections (oooo) (pppp), (qqqq)1., and (qqqq)3. through (qqqq)8. which are not in the SIP.
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[FR Doc. 2020–09602 Filed 5–28–20; 8:45 am]

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Proposed Rules

Federal Register
Vol. 85, No. 104
Friday, May 29, 2020

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.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 315

RIN 3206–AM76

Noncompetitive Appointment of Certain Military Spouses

AGENCY: Office of Personnel Management.

ACTION: Proposed rule; request for comments.

SUMMARY: The Office of Personnel Management (OPM) is proposing regulations which will modify the provisions governing the recruitment and employment of certain military spouses in Federal agencies to conform to statutory mandates affecting the rules governing this authority and to carry out certain provisions of Executive Order 13832 of May 9, 2018, *Enhancing Noncompetitive Civil Service Appointments of Military Spouses.* OPM is proposing to revise the current text to: Conform the eligibility criteria for appointment of military spouses to intervening statutory requirements and add agency reporting requirements.

DATES: Comments must be received on or before July 28, 2020.

ADDRESSES: You may submit comments, identified by the docket number or Regulation Identifier Number (RIN) for this proposed rulemaking, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for sending comments.

All submissions must include the agency name and docket number or RIN for this rulemaking. Please arrange and identify your comments on the regulatory text by subpart and section number; if your comments relate to the supplementary information, please refer to the heading and page number. All comments received will be posted without change, including any personal information provided. Please ensure your comments are submitted within the specified open comment period. Comments received after the close of the comment period will be marked ''late,'' and OPM is not required to consider them in formulating a final decision. Before acting on this proposal, OPM will consider all comments we receive on or before the closing date for comments. Changes to this proposal may be made in light of the comments we receive.

FOR FURTHER INFORMATION CONTACT: Michelle Glynn, telephone: 202–606–1571, fax: 202–606–3340, TDD: 202–418–3134, or email: *michelle.glynn@opm.gov.*

SUPPLEMENTARY INFORMATION: OPM is making these changes to give effect to provisions contained in the Fiscal Year (FY) 2013 National Defense Authorization Act (NDAA), Public Law 112–239, section 566, subsequently codified at 5 U.S.C. 3330d; the FY 2017 NDAA, Public Law 114–328, section 1131, which amended 5 U.S.C. 3330d(c); and the FY 2019 NDAA, Public Law 115–232, section 573, which temporarily amends 5 U.S.C. 3330d and imposes a temporary reporting requirement on OPM; as well as certain provisions of E.O. 13832 imposing permanent agency reporting requirements.

2008, E.O. 13473—The Original Authority and OPM's Implementing Regulations

On September 25, 2008, the President issued Executive Order (E.O.) 13473 allowing agencies to make noncompetitive appointments of certain military spouses of members of the Armed Forces. OPM implemented this E.O. via final regulations which were published in the **Federal Register** (FR) on August 12, 2009, at 74 FR 40471, and amended on August 31, 2011, at 76 FR 54071. OPM's rules implemented the noncompetitive hiring authority for certain military spouses created by the Executive Order. Under this hiring authority, eligible spouses included, subject to other criteria specified in the final rule, the following categories of military spouses: Those who were relocating with their service member spouse as a result of permanent change of station (PCS) orders, spouses of service members who incurred a 100 percent disability because of the service member's active duty service, and the un-remarried widows or widowers of service members killed while on active duty. For a spouse using this authority pursuant to a member's PCS orders, OPM's implementing rules restricted the number of permanent appointments an eligible spouse could receive to one per each set of PCS orders. (OPM did not restrict the number of permanent appointments the spouse of a disabled or deceased member of the Armed Forces could receive under its original regulations.) OPM's original implementing rules also established a two-year limitation on the period of time during which the authority could be used.

2011, 76 ***Federal Register*** *54071*—In 2011, OPM amended these rules to eliminate the 2-year eligibility limitation for spouses of service members who incurred a 100 percent disability or who were killed while on active duty. 76 FR 54071 (Aug. 31, 2011). This change was based upon findings provided by the Department of the Navy demonstrating that spouses experienced difficulty using the authority, in these circumstances, within the 2 years provided. 76 FR 13100, 13100 (March 10, 2011).

The FY 2013 NDAA

On January 2, 2013, the President signed the FY 2013 NDAA. Section 566(a) of this Act codified in statute, at 5 U.S.C. 3330d, the hiring authority previously created by E.O. 13743 and added a provision limiting the spouse of a disabled or deceased member of the Armed Forces to one permanent appointment pursuant to this authority. OPM is proposing to amend the current text of its regulations to reflect this change and expressly limit to one the number of permanent appointments an eligible spouse of a disabled or deceased member of the Armed Forces may receive under these provisions. We are proposing these changes to conform our regulations to this statutory provision. When positing a job opportunity announcement (JOA) on USAJOBS agencies can specify this requirement in the JOA and/or use the assessment questionnaire to ask whether military spouse applicants have previously received a permanent appointment under this hiring authority.

The FY 2013 NDAA also addressed the question of geographic location. OPM's current regulation at § 315.612(c)(3) states that, for spouses of relocating members, use of the military

spouse authority ''is limited to the geographic area, as specified on the service member's permanent change of station orders,'' and that this area ''includes the service member's duty station and the surrounding area from which people reasonably can be expected to travel daily to and from work,'' but also provides that ''[t]he head of an agency, or his or her designee, may waive this limitation . . . if no Federal agency exists in the spouse's geographic area.'' The FY 2013 NDAA, however, addressed geographic area in a manner that superseded an aspect of OPM's regulations. The statute provided that the appointment of a relocating spouse ''may only be to a position the duty station for which is within the geographic area of the permanent duty station of the member of the Armed Forces, *unless there is no agency with a position with a duty station within the geographic area of the permanent duty station of the member of the Armed Forces.*'' (Emphasis supplied). That statute, therefore, eliminated the need for the relocating spouse to obtain a waiver in order for the spouse to apply, or an agency to consider the spouse, for a position outside the geographic area when no agency exists in the spouse's geographic area. OPM proposes to amend the text of its current regulation to align with this provision, in a new paragraph (c)(5). In light of subsequent developments, discussed below, however, neither the changes imposed by the FY 2013 NDAA nor the conforming amendments to OPM's regulation will take effect until 12:01 a.m. Eastern Time on August 13, 2023.[1]

The FY 2017 NDAA

Currently, the text of OPM's regulations, as amended through 2011, purports to limit the eligibility of relocating spouses of members of the Armed Forces to 2 years from the date of the Armed Forces member's PCS orders. On December 23, 2016, however, the President signed the FY 2017 NDAA. Section 1131 of that Act amended section 3330d(c) of title 5, United States Code to specify that, thereafter, there would be no time limitation on eligibility for relocating spouses of the Armed Forces. Under the amended statute, a spouse of a member of the Armed Forces relocating pursuant to the member's PCS orders would remain eligible for noncompetitive appointment under this section for the duration of the spouse's relocation to the permanent duty station of the service member. OPM proposes to amend its regulations to align with this provision, although this statutory provision and the conforming OPM amendments also will have no effect until August 13, 2023.[2]

2018, E.O. 13832

On May 9, 2018, the President issued E.O. 13832, which was intended to enhance noncompetitive civil service appointments of military spouses. The E.O. states the policy of the United States is to enhance employment support for military spouses. Agencies are directed, to the greatest extent possible consistent with hiring needs, to indicate in their Job Opportunity announcement (JOA) for positions in the competitive service that they will consider candidates under the noncompetitive military spouse authority in addition to any other hiring authority the JOA indicates the agency will consider. Section 3(b) of the E.O. directs agencies to actively advertise and promote the military spouse hiring authority and solicit applications from military spouses for positions advertised via USAJOBS and any other means the agency wishes to use.

Section 3(f) of the Executive Order imposes an annual reporting requirement upon agencies, beginning in December 2019, so that OPM can fulfill its obligation in section 4 to provide an annual report to the President regarding the implementation of his order. The Executive Order requires agencies to report to OPM and the Department of Labor on the following information:

- The number of positions made available under the military spouse hiring authority,
- the number of applications submitted under the military spouse hiring authority,
- the number of military spouses appointed under the military spouse hiring authority during the preceding fiscal year, and
- actions taken to advertise the military spouse hiring authority, and any other actions taken to promote the hiring of military spouses.

OPM is proposing to amend its regulations to add this requirement to the permanent text. OPM proposes to amend its permanent regulations to add a new paragraph (h) to align with this provision.

Agencies will have to decide how they will keep track of the information collected from the effective date of E.O. 13832, to the effective date of this proposal as this E.O. required agencies to begin reporting by December 2019. The timeframes regarding OPM's issuance of final regulations for this hiring authority does not impact the reporting date required by the E.O.

As stated in E.O. 13832 dated May 9, 2018, agencies are required to begin reporting to OPM and the Department of Labor in Fiscal Year 2019, by December 31 of each year. On March 1, 2019, and September 27, 2019, OPM issued Memorandums for Human Resources Directors advising agencies that they must submit reports no later than December 31, 2019. As a reminder, these OPM policy guidance memorandums, which include information on agency reporting requirements, are located on the OPM website, on the Chief Human Capital Officer's webpage at: *https://www.chcoc.gov/content/recent-changes-noncompetitive-hiring-authority-military-spouses* and *https://www.chcoc.gov/content/agency-non-competitive-hiring-authority-military-spouses-annual-reporting*. As contained in proposed section 315.612(h)(1), E.O. 13832 further requires agencies to report separately to the Department of Labor. OPM will remind agencies of this requirement in its supplemental policy Q&A guidance.

The FY 2019 NDAA, discussed immediately below, contained a temporary reporting requirement, apparently limited to the spouses of current members of the Armed Forces on active duty, regardless of whether or not they relocate with the member. See Public Law 115–232 section 573(d) (Aug. 13, 2018). That temporary reporting requirement overlaps the requirement in the E.O. to a degree but is also somewhat different. In other words, the data being reported is a subset of the data being reported in accordance with the E.O. We discuss our resolution of these separate requirements below.

FY 2019 NDAA

On August 13, 2018, the President signed the FY 2019 NDAA. Section 573 of the NDAA, which sunsets in five years from the date of enactment (*i.e.,* the end of the day on August 12, 2023), temporarily amends several provisions of 5 U.S.C. 3330d, governing the military spouse noncompetitive hiring authority, including the need for spouses of members currently on active duty to meet existing eligibility criteria relating to relocation pursuant to PCS

[1] The FY 2019 NDAA temporarily makes spouses of active duty members generally eligible without having to establish a relocation pursuant to PCS orders. Accordingly, at present, there is no need to reference conditions of eligibility under that prong of the original authority. That provision will expire on August 12, 2023.

[2] See note 1, above.

orders. Section 573(a) eliminates the eligibility criterion that was based on the contingency that the spouse was relocating with a military member on PCS orders and replaced it with one that includes all spouses of members of the armed forces on active duty. Section 573(a) also eliminates 5.U.S.C. 3330d(c), *Special rules regarding relocating spouses*. In accordance with revised 5 U.S.C. 3330d(b), the head of an agency may now appoint noncompetitively: The spouse of a member of the armed forces on active duty, or a spouse of a 100 percent disabled or deceased member of the armed forces. The NDAA makes any spouse of a military member on active duty eligible for noncompetitive appointment under this hiring authority and eliminates geographic restrictions that would otherwise apply under the statute.

On March 1, 2019, OPM issued a Memorandum for Chief Human Capital Officers advising of two provisions (FY 2019 NDAA and E.O. 13832) that would significantly impact this hiring authority; and imposes temporary reporting requirements. As another reminder, OPM encourages readers to view OPM's more detailed policy guidance at: *https://www.chcoc.gov/content/recent-changes-noncompetitive-hiring-authority-military-spouses*.

Because of the sunset provision, OPM's proposed rule provides both for temporary exceptions to the permanent rules necessitated by the FY 2019 NDAA and for eventual changes to the permanent regulations, which will be revived on August 13, 2023 but which do not yet conform to changes effected by the FY 2013 and 2017 NDAAs. These changes appear at §§ 315.612(a) *Agency Authority,* 315.612(b) *Definitions,* 315.612(c) *Eligibility,* 315.612(d) *Conditions,* and 315.612(e) *Proof of Eligibility*. Renumbering of these sections is proposed where appropriate. The definition of *Permanent change of station* was intentionally removed as it no longer applies for the next five years (*i.e.,* until August 13, 2023).

As noted above, the FY 2019 NDAA also contained a temporary reporting requirement specific to the spouses of active duty service members that will sunset on August 13, 2023. Section 573(d) requires agencies to report to OPM on an annual basis (*i.e.,* by December 31 of each year) on:

- The number of relocating and non-relocating spouses of current military members appointed under this authority;
- the types of positions filled; and
- the effectiveness of this hiring authority.

OPM is proposing to add temporary text to section 315.612(h)(2) to cover agency reporting requirements that differ from the President's requirement. The proposed rule at subsection 315.612(h)(2)(ii) requires agencies to collect information on both types of spouses and to record these distinctions as appointments are made for inclusion in their reports to OPM.

Proposed section 315.612(h)(2)(ii) requires agencies to report on the types of positions filled under this authority. OPM is proposing that agencies provide data specific to the title, series, and grade level of positions filled under this authority.

Agencies must comply with the reporting requirements in both proposed 5 CFR 315.612(h)(1) and (2) until August 13, 2023. On August 13, 2023, and thereafter agencies will comply with only proposed 5 CFR 315.612(h)(1). OPM is proposing to make these necessary changes to conform our regulations to permanent changes to 5 U.S.C. 3330d required by the 2013 and 2017 NDAAs and a new reporting requirement imposed by E.O. 13832, as well to reflect the temporary requirements added by the 2019 NDAA. Following sunset of the temporary requirements, OPM's regulations will be deemed to revert to the permanent regulations, *i.e.,* the current regulations, as revised pursuant to the FY 2013 NDAA and the FY 2017 NDAA.

How agencies should report in 2023, will depend on whether Congress chooses to continue these provisions after the August 13, 2023, date. In the absence of Congress passing any new statutes on this issue, agencies should comply with only proposed 5 CFR 315.612(h)(1) pertaining to E.O. 13832.

Regulatory Flexibility Act

I certify that this regulation will not have a significant impact on a substantial number of small entities because it applies only to Federal agencies and employees.

E.O. 13563 and E.O. 12866, Regulatory Review

This rule has been reviewed by the Office of Management and Budget in accordance with E.O. 13563 and 12866.

Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs

This rule is not an E.O. 13771 regulatory action because this rule is not significant under E.O. 12866.

E.O. 13132, Federalism

This regulation will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant preparation of a Federalism Assessment.

E.O. 12988, Civil Justice Reform

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

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local or tribal governments of more than $100 million annually. Thus, no written assessment of unfunded mandates is required.

Congressional Review Act

This action pertains to agency management, personnel and organization and does not substantially affect the rights or obligations of nonagency parties and, accordingly, is not a ''rule'' as that term is used by the Congressional Review Act (Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA)). Therefore, the reporting requirement of 5 U.S.C. 801 does not apply.

Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35)

This final regulatory action will not impose any additional reporting or recordkeeping requirements under the Paperwork Reduction Act.

List of Subjects in 5 CFR Part 315

Government employees.

Office of Personnel Management.

Alexys Stanley,

Regulatory Affairs Analyst.

Accordingly, OPM is proposing to amend 5 CFR part 315 as follows:

PART 315—CAREER AND CAREER–CONDITIONAL EMPLOYMENT

■ 1. The authority citation for part 315 is revised to read as follows:

Authority: 5 U.S.C. 1302, 3301, and 3302; E.O. 10577, 3 CFR, 1954–1958 Comp. p. 218, unless otherwise noted; and E.O. 13162.

Secs. 315.601 and 315.609 also issued under 22 U.S.C. 3651 and 3652.

Secs. 315.602 and 315.604 also issued under 5 U.S.C. 1104.

Sec. 315.603 also issued under 5 U.S.C. 8151.

Sec. 315.605 also issued under E.O. 12034, 3 CFR, 1978 Comp. p. 111.

Sec. 315.606 also issued under E.O. 11219, 3 CFR, 1964–1965 Comp. p. 303. Sec. 315.607 also issued under 22 U.S.C. 2560.

Sec. 315.608 also issued under E.O. 12721, 3 CFR, 1990 Comp. p. 293.

Sec. 315.610 also issued under 5 U.S.C. 3304(c).

Sec. 315.611 also issued under 5 U.S.C. 3304(f).

Sec. 315.612 also issued under E.O. 13473, Pub. L. 112–239, Sec. 566; Pub. L. 114–328, Sec. 1131; Pub. L. 115–232, Sec. 573; and E.O. 13832.

Sec. 315.708 also issued under E.O. 13318, 3 CFR, 2004 Comp. p. 265.

Sec. 315.710 also issued under E.O. 12596, 3 CFR, 1978 Comp. p. 264, also issued under E.O. 13832 and Pub. L. 115–232, Sec. 573.

Subpart F—Career or Career-Conditional Appointment Under Special Authorities

■ 2. In § 315.612, revise paragraphs (a) through (e) and add paragraph (h) to read as follows:

§ 315.612 Noncompetitive appointment of certain military spouses.

(a) *Agency authority.* In accordance with the provisions of this section, an agency head may appoint noncompetitively a spouse of a member of the armed forces serving on active duty, a spouse of a 100 *percent* disabled service member injured while on active duty, or the un-remarried widow or widower of a service member who was killed while performing active duty.

(b) *Definitions.* For purposes of this section:

(1) *Active duty* means full-time duty in the armed forces, including full-time National Guard duty, except that for Reserve Component members the term ''active duty'' does not include training duties or attendance at service schools.

(2) *Armed forces* has the meaning given that term in 10 U.S.C. 101.

(3) *Duty station* means the permanent location to which a member of the armed forces is assigned for duty as specified on the individual's permanent change of station (PCS) orders.

(4) *Member of the armed forces* or *service member* means an individual who:

(i) Is serving on active duty in the armed forces or serving under orders specifying the individual is called or ordered to active duty for more than 180 consecutive days;

(ii) Retired or was released or discharged from active duty in the armed forces and has a disability rating of 100 percent as documented by the Department of Veterans Affairs; or

(iii) Was killed while serving on active duty in the armed forces.

(5) *Spouse* means the husband or wife of a member of the armed forces.

(c) *Eligibility.* (1) A spouse of a member of the armed forces as defined in paragraph (b)(4)(i) of this section must be currently married to the member of the armed forces on active duty. For appointments made on or after August 13, 2023, the following additional criteria must be met for eligibility for appointment (for appointments made prior to or on August 12, 2023, these criteria do not apply):

(i) The member of the armed forces must have received orders authorizing a permanent change of station.

(ii) The spouse must have married the member of the armed forces on, or prior to, the date of such orders authorizing the permanent change of station.

(iii) The spouse must have relocated or is relocating with the member of the armed forces to the new duty station specified in the documentation ordering the permanent change of station.

(2) A spouse of a member of the armed forces as defined in paragraph (b)(4)(ii) of this section must be currently married to the member of the armed forces.

(3) A spouse of a member of the armed forces as defined in paragraph (b)(4)(iii) of this section must be the un-remarried widow or widower of the member of the armed forces killed on active duty in the armed forces.

(4) Except as indicated in paragraph (c)(5) of this section, noncompetitive appointment of eligible spouses under this section are not restricted to a geographical location.

(5) Effective August 13, 2023, the noncompetitive appointment of a relocating spouse of a member of the armed forces as defined in paragraph (b)(4)(i) of this section is limited to the geographic area of the permanent duty station of the member of the armed forces, unless there is no agency with a position within the geographic area of the permanent duty station of the member of the armed forces.

(d) *Conditions.* (1) In accordance with the provisions of this section, a spouse is eligible for noncompetitive appointment:

(i) From the date of documentation verifying the spouse's marriage to a member of the armed forces as defined in paragraph (b)(4)(i) of this section, where the spouse seeks appointment based upon marriage to an active duty member of the armed forces;

(ii) From the date of documentation verifying that the member of the armed forces is 100 percent disabled, where the spouse seeks appointment based upon marriage to a member defined in paragraph (b)(4)(ii) of this section; or

(iii) From the date of documentation verifying that the member of the armed forces was killed while on active duty where the spouse seeks appointment as the widow or widower of a member defined in paragraph (b)(4)(iii) of this section.

(2) The spouse of a member of the armed forces as defined in (b)(4)(i) of this section may receive unlimited noncompetitive appointments under this section to permanent positions through August 12, 2023. Effective August 13, 2023, the spouse of such a member may receive a noncompetitive appointment under this section if the member receives permanent change of station orders and is limited to one such appointment per permanent change of station.

(3) A spouse of a member of the armed forces as defined in (b)(4)(ii) or (iii) of this section may receive only one noncompetitive appointment under this section to a permanent position.

(4) Any law, Executive order, or regulation that disqualifies an applicant for appointment also disqualifies a spouse for appointment under this section.

(e) *Proof of eligibility.* (1) Prior to appointment, the spouse of a member of the armed forces as defined in paragraph (b)(4)(i) of this section must submit to the employing agency copies of documentation verifying active duty status and documentation verifying marriage to the member of the armed forces (*i.e.,* a marriage certificate or other legal documentation verifying marriage). For appointments made on or after August 13, 2023, the spouse must also submit to the employing agency a copy of the service member's orders reflecting a permanent change of station, dated August 13, 2023 or later. (For appointments made on or before August 12, 2023, this requirement does not apply.)

(2) Prior to appointment, the spouse of a member of the armed forces as defined in paragraph (b)(4)(ii) of this section must submit to the employing agency copies of:

(i) Documentation showing the member of the armed forces retired, or was released or discharged from active duty, with a disability rating of 100 percent; and

(ii) Documentation verifying marriage to the member of the armed forces (*i.e.,* a marriage license or other legal documentation verifying marriage).

(3) Prior to appointment, the spouse of a member of the armed forces as defined in paragraph (b)(4)(iii) of this section must submit to the employing agency copies of:

(i) Documentation showing the member was released or discharged from active duty due to his or her death while on active duty;

(ii) Documentation verifying the member of the armed forces was killed while serving on active duty; and

(iii) Documentation verifying the widow or widower's marriage to the member of the armed forces (*i.e.,* a marriage license or other legal documentation verifying marriage); and

(iv) A statement certifying that the individual seeking to use the authority is the un-remarried widow or widower of the service member.

* * * * *

(h) *Agency Reporting Requirements.* (1) As required by Executive Order 13832, each agency shall report annually (by December 31st of each year) to OPM and the Department of Labor on:

(i) The number of positions made available under the military spouse hiring authority;

(ii) The number of applications submitted under the military spouse hiring authority;

(iii) The number of military spouses appointed under the military spouse hiring authority during the preceding fiscal year; and

(iv) Actions taken to advertise the military spouse hiring authority, and any other actions taken to promote the hiring of military spouses.

(2) As required by section 573(d) of Public Law 115–232 section 573(d), each agency shall report annually until August 13, 2023, and separate from the report required in paragraph (h)(1) of this section on the following:

(i) The number of relocating and non-relocating spouses of current military members appointed under this authority;

(ii) The types of positions filled (by title, series, and grade level); and

(iii) The effectiveness of this hiring authority.

(3) Agencies should send their reports electronically to OPM's Employee Services at *militaryspouse@opm.gov*.

(4) Agencies are also required to send their reports separately and directly to Department of Labor (DOL) at *Merens.Nathan.P@DOL.gov*.

[FR Doc. 2020–10768 Filed 5–28–20; 8:45 am]

BILLING CODE 6325–39–P

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 50 and 52

RIN 3150–AJ68

[NRC–2015–0225]

Emergency Preparedness for Small Modular Reactors and Other New Technologies

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule and guidance; correction.

SUMMARY: The Nuclear Regulatory Commission (NRC) is correcting a proposed rule that appeared in the **Federal Register** on May 12, 2020. The NRC is proposing to amend its regulations to include new alternative emergency preparedness requirements for small modular reactors and other new technologies, such as non-light-water reactors and certain non-power production or utilization facilities. This action is necessary to correct a definition.

DATES: Effective May 29, 2020.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Website: Go to https://www.regulations.gov* and search for Docket ID NRC–2015–0225. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov*. For technical questions contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Email comments to Rulemaking.Comments@nrc.gov*. If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.

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

FOR FURTHER INFORMATION CONTACT: Robert Beall, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington DC 20555; telephone: 301–415–3874; email: *Robert.Beall@nrc.gov*; or Eric Schrader, Office of Nuclear Security and Incident Response; telephone: 301–287–3789; email: *Eric.Schrader@nrc.gov*; both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION: The NRC published a proposed rule in the **Federal Register** on May 12, 2020 (85 FR 28436), to amend its regulations to create an alternative emergency preparedness framework for small modular reactors and other new technologies.

On page 28460, in the first column, second paragraph, fourth line correct the definition ''*Non-power production or utilization facility*'' to read as follows: *Non-power production or utilization facility* means a production or utilization facility, licensed under § 50.21(a) or (c), or § 50.22, as applicable, that is not a nuclear power reactor or a production facility as defined under paragraphs (1) and (2) of the definition of *Production facility* in this section.

Dated May 20, 2020.

For the Nuclear Regulatory Commission.

Pamela J. Shepherd-Vladimir,

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

[FR Doc. 2020–11228 Filed 5–28–20; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0049; Product Identifier 2017–CE–031–AD]

RIN 2120–AA64

Airworthiness Directives; Textron Aviation Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (SNPRM); reopening of comment period.

SUMMARY: The FAA is revising an earlier proposal for certain Textron Aviation Inc. (Textron) Model 172N, 172P, 172Q, 172RG, F172N, F172P, FR172K, R172K, 182E, 182F, 182G, 182H, 182J, 182K, 182L, 182M, 182N, 182P, 182Q, 182R, T182, F182P, F182Q, F182RG, R182, TR182, 206, P206/TP206, U206/TU206, 207/T207, 210–5 (205), 210–5A (205A), 210B, 210C, 210D, 210E, 210F, and T210F airplanes. This action revises the

notice of proposed rulemaking (NPRM) by modifying the estimated costs of the proposed AD, the repetitive inspection intervals, and the credit allowed for previous actions; clarifying the inspection instructions for airplanes with the service kit installed; correcting the contact information for obtaining the service information; and adding a reporting requirement to collect the inspection results. The FAA is proposing this airworthiness directive (AD) to address the unsafe condition on these products. Since these actions would impose an additional burden over those in the NPRM based on comments from commenters, the FAA is reopening the comment period to allow the public the chance to comment on these changes.

DATES: The comment period for the NPRM published in the **Federal Register** on February 1, 2018 (83 FR 4605), is reopened.

The FAA must receive comments on this SNPRM by July 13, 2020.

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

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

For service information identified in this SNPRM, contact Textron Aviation Inc., Textron Aviation Customer Service, One Cessna Blvd., Wichita, Kansas 67215; telephone: (316) 517–5800; email: *customercare@txtav.com;* internet: *https://support.cessna.com*. You may review this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0049; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this SNPRM, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Bobbie Kroetch, Aerospace Engineer, Wichita ACO Branch, 1801 Airport Road, Room 100, Wichita, Kansas 67209; telephone: (316) 946–4155; fax: (316) 946–4107; email: *bobbie.kroetch@faa.gov* or *Wichita-COS@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2018–0049; Product Identifier 2017–CE–031–AD'' at the beginning of your comments. The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this SNPRM. The FAA will consider all comments received by the closing date and may amend this SNPRM because of those comments.

The FAA will post all comments, without change, to *https://www.regulations.gov,* including any personal information you provide. The FAA will also post a report summarizing each substantive verbal contact received about this SNPRM.

Discussion

The FAA issued an NPRM to amend 14 CFR part 39 by adding an AD that would apply to certain Textron (type certificate previously held by Cessna Aircraft Company) Model 172N, 172P, 172Q, 172RG, F172N, F172P, FR172K, R172K, 182E, 182F, 182G, 182H, 182J, 182K, 182L, 182M, 182N, 182P, 182Q, 182R, T182, F182P, F182Q, F182RG, R182, TR182, 206, P206/TP206, U206/TU206, 207/T207, 210–5 (205), 210–5A (205A), 210B, 210C, 210D, 210E, 210F, and T210F airplanes. The NPRM published in the **Federal Register** on February 1, 2018 (83 FR 4605). The NPRM was prompted by a report from an operator of one of the affected Textron airplanes that cracks were found in the lower area of the forward cabin doorpost bulkhead. The NPRM proposed to require repetitively inspecting the lower area of the forward cabin doorposts at the strut attach fitting for cracks and repairing any cracks found by modifying the area with the applicable service kit.

Comments

The FAA gave the public the opportunity to comment on the NPRM. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Withdraw the NPRM

Matt Gunsch stated that cracking at the location identified in the NPRM was not observed while performing annual inspections on hundreds of Cessna airplanes as a mechanic with an Inspection Authorization. The commenter explained that these inspections were on airplanes from the Model 172A to the newest restart airplane, with some flown as little as 25 hours a year to others that were flown l,000 hours a year, all with no evidence of cracking at this location. The FAA infers the commenter would like to see the NPRM withdrawn.

The FAA disagrees. The FAA's investigation revealed more than four dozen similar cracks on Textron Model 100- and 200-series airplanes. The FAA has not changed this proposed AD based on this comment.

Requests To Change the Repetitive Inspection Compliance Intervals

Mark Stephenson, Ronald Welch, the Aircraft Owners and Pilots Association (AOPA), Kermit Bunde, Matt Gunsch, Howard Nelson, and an anonymous commenter requested the FAA change the compliance time for the repetitive inspection intervals to hours TIS only and remove the 12-month calendar time inspection requirement. Neal Bachman suggested the compliance time be based on take off and landing cycles. Most of these commenters stated the cracking identified in the proposed AD was attributed to metal fatigue, which is driven by usage, not calendar time. Several commenters noted that an annual repetitive inspection adds an unnecessary burden for operators of low-use airplanes that may accumulate less than 1,000 hours TIS per year. The anonymous commenter stated that a repetitive inspection every 12 months was unjustified and unsupported because the FAA did not include in the AD docket crack-propagation math models or show raw data indicating the number of airplanes with cracks, their associated TIS, or the crack lengths.

Craig Morton requested the FAA change the multiple compliance time interval from ''whichever occurs first'' to ''whichever occurs later.''

David Scott requested that the FAA increase the repetitive interval depending on airplane configuration.

The FAA partially agrees. The FAA did not provide the data requested by

the anonymous commenter because the raw data relied upon by the FAA in its risk analysis did not include crack lengths. The FAA agrees to revise the calendar time requirement because a repetitive inspection annually does not account for low use airplanes. The FAA has adjusted the proposed repetitive inspection interval from 12 months or 1,000 hours TIS to 36 calendar months or 1,000 hours TIS. The FAA has determined this extended compliance time adequately addresses the identified unsafe condition. In addition, this compliance time corresponds with the manufacturer's guidance, for certain airplanes, that is published in supplemental inspection documents (SIDs) and is supported by the fleet history. The FAA disagrees with providing an allowance for takeoff and landing cycles because there is insufficient data to support inspection intervals based on this aspect of an airplane's usage. Also, FAA regulations do not require all operators to maintain records of landing and takeoff cycles. The FAA also disagrees with the requests to base the inspection solely on flight hours and to increase the inspection interval. In developing appropriate compliance times for this proposed AD, the FAA considered the urgency associated with the subject unsafe condition, the manufacturer's recommended compliance times, the availability of parts, and the practical aspect of accomplishing the required inspection and any on-condition actions. In light of these factors, the FAA determined the proposed compliance times are appropriate and address the identified unsafe condition.

Request To Decrease the Initial Inspection Compliance Time

An anonymous commenter suggested the FAA require the initial inspection before 4,000 hours TIS. The commenter stated that cracking might occur in airplanes before the 4,000 hours TIS identified in the proposed AD.

The FAA partially agrees. The FAA agrees that unverified reports indicate cracking may occur before an airplane accumulates 4,000 hours TIS. However, the FAA disagrees with reducing the compliance time for the initial inspection at this time because the data available from the manufacturer and from the FAA service difficulty reporting system does not contain sufficient information to justify it. The FAA has added a reporting requirement to the proposed AD to help the FAA collect more data to determine if the cracking is occurring at an earlier period. The FAA will analyze the reporting results and may take further rulemaking action.

Requests To Clarify the Repetitive Inspection Instructions

Two commenters requested the FAA clarify the repetitive inspection instructions for airplanes that have a service kit installed. Adam Ondrajka noted it is more difficult to do the inspection after installation of the service kit because it covers some of the area susceptible to cracking. Hageland Aviation Services, Inc. (Hageland Aviation) requested the proposed AD be revised to include verbiage that allows the inspection to be performed with the service kit remaining in place, and inspecting for any cracking that has propagated past the boundaries of the kit. This commenter also stated that the term ''to the fullest extent'' in the repetitive inspection instructions for airplanes with a service kit installed is unclear and could be interpreted to require removal of the kit to complete the inspection.

The FAA agrees. The FAA has changed the proposed inspection language to clarify the service kit should not be removed during the inspections and to inspect for cracks extending beyond the modified parts.

Requests Regarding the Service Kits

AOPA requested the FAA allow the installation of the service kit to terminate the repetitive inspection requirements of the proposed AD. AOPA and Adam Ondrajka noted that installation of the kit is terminating action in Cessna Mandatory Service Bulletins SEB 93–5R1 and SEB 95–19, and the FAA did not provide justification or reasoning in the NPRM for continuing the repetitive inspections after installation of the kit.

Neal Bachman requested the FAA encourage the installation of the service kit preemptively to prevent future cracking, and stated that if ongoing inspections are required after the service kit is installed then the kit is inadequate.

The FAA partially agrees. Owners may voluntarily install the service kit, as neither the NPRM nor this SNPRM would prohibit the installation of the service kit prior to observed cracking. The structure added by the service kit reinforces the critical area on which cracking has been found. However, the manufacturer did not provide sufficient evidence that installation of the service kits corrects the unsafe condition and therefore warrants discontinuing the inspections. In addition, the FAA has received unconfirmed reports of cracking extending beyond the repair doubler that is installed as part of the kit. At this time, sufficient information is not available to determine the cause of the continued cracking. Therefore, the FAA has added a reporting requirement to this SNPRM to evaluate the crack development.

Comment Regarding Variable Time Limit for Kit Installation

Mark Stephenson requested the FAA change the compliance time for installing the service kit after crack detection to a variable compliance time based on the size, number, or severity of the identified cracking. The commenter noted that the proposed AD specifies installing the service kit before further flight if cracks are found, while at the same time specifying a 1,000-hour repeat inspection of the area if no cracks are found. The commenter stated that therefore the FAA is accepting that flight with cracks is acceptable for periods approaching 1,000 hours and concluded the logic for the requirement to incorporate the service kit before further flight is flawed.

The FAA disagrees. There is insufficient data on crack growth rate to support flight with known cracks without installation of the service kit. Therefore, this proposed AD would not allow variable compliance times based on the size, number, or severity of the identified cracking. The installation of the service kit reinforces the cracked area. The FAA has not changed this SNPRM based on this comment.

Concern for Parts Availability

Urban Moore, Hageland Aviation, Bruce Thomas, and Paul Gryko expressed concern that the proposed AD may ground airplanes after cracks are identified because of the unavailability of parts. The commenters indicated that waiting times for some of the service kits were several months.

The FAA recognizes the demand for the service kits following the issuance of the proposed AD is likely to increase. However, the FAA has determined that the proposed actions and compliance times are necessary to address the identified unsafe condition. The FAA has not changed this proposed AD based on this comment. However, operators may request approval of an alternative method of compliance (AMOC) to extend the compliance times under the provisions of paragraph (m) of this proposed AD. The operator must justify in the request that an extension of the compliance time will provide an adequate level of safety.

Request for Specific Part Numbers

Urban Moore noted that Textron would not provide the specific part numbers for each item included in the service kits.

The FAA disagrees. The applicable service kits identify the part numbers required for the kit installation. The FAA will post in the AD docket all service documents incorporated by reference when the FAA issues the final rule. Until then, and as specified in the **ADDRESSES** section of the NPRM and this SNPRM, interested parties may contact Textron for a copy of the service information identified in this SNPRM. A party may also view the service information in person at the FAA's offices in Kansas City, Missouri.

Request To Include the Possibility of Extended Cracks

Textron suggested the FAA change the language in the proposed AD to reflect that cracks could extend beyond the doublers installed in accordance with the service kits, if an operator installed a service kit before the AD was released.

The FAA agrees. The FAA has added language to paragraphs (g) and (h)(2) of this proposed AD to address potential cracking on airplanes with the service kits installed.

Request To Make Service Information Available

Matt Gunsch commented about the difficulty obtaining the service bulletins that are the basis of the proposed AD and requested the FAA include the referenced service documents in the AD Docket.

The FAA partially agrees. The FAA will post in the AD docket all service documents incorporated by reference when the FAA issues the final rule. Until then, and as specified in the **ADDRESSES** section of the NPRM and this SNPRM, interested parties may contact Textron for a copy of the service information identified in this SNPRM. A party may also view the service information in person at the FAA's offices in Kansas City, Missouri.

Request To Update Service Information

Textron requested the FAA update references to the service bulletin and service kit information in the proposed AD to reflect the latest revision levels.

The FAA agrees. The FAA has updated the service information in this proposed AD accordingly.

Request To Provide Credit for Airplanes With SK206–42 or SK206–42A Installed

Textron requested the FAA clarify the credit in paragraph (k)(3) of the proposed AD for Model 207 and T207 airplanes that have installed a service kit in accordance with Cessna Single Engine Service Bulletin SEB 93–5, dated March 26, 1993. Specifically, Textron asked whether owners/operators are expected to remove the kit and install a new kit.

The FAA agrees to clarify the credit for Model 207 and T207 airplanes. The FAA has revised paragraph (k)(3) of the NPRM and redesignated it as paragraph (k)(2)(i) in this SNPRM. As now proposed, paragraph (k)(2)(i) specifies that the reinforcement detailed in Cessna Single Engine Service Kit SK207–19A, dated May 29, 2019, must be done to receive credit for previous installations. As specified in Cessna Single Engine Service Kit SK207–19A, dated May 29, 2019, the reinforcement can be done on airplanes with a previously installed SK206–42() kit.

Request To Allow Credit for Previous Actions

Hageland Aviation, Jason Vink, Stephen Greenwood, Adam Ondrajka, AOPA, Textron, and an anonymous commenter requested the FAA allow credit for initial inspections and service kit installations in accordance with Cessna Service Bulletins SEB 93–5, SEB 93–5 Revision l, and SEB 95–19. Hageland Aviation stated that failing to give credit could affect intrastate aviation within the state of Alaska. Adam Ondrajka stated that paragraphs (k)(1)(v) and (k)(3) of the proposed AD include contradictory language for previous repairs completed on Model 207 and T207 airplanes. Textron and an anonymous commenter requested credit for inspections that have been previously completed.

The FAA partially agrees. Paragraph (f), ''Compliance,'' of both the NPRM and this SNPRM states compliance is required ''unless already done,'' which allows credit for any AD action completed before the effective date of the AD.

The FAA has revised paragraphs (k)(1) and (2) of this SNPRM to provide credit for most airplane models that have installed the service kit using Cessna Single Engine Service Bulletin SEB 93–5, dated March 26, 1993; or Cessna Single Engine Service Bulletin SEB 93–5, Revision 1, dated September 8, 1995. The FAA has also revised paragraph (k)(3) (redesignated as paragraph (k)(2)(i) in this SNPRM) to allow credit for Model 207, T207, 207A, and T207A airplanes that have installed the service kit if additional reinforcement has also been done.

The FAA disagrees that the language in paragraphs (k)(1)(v) and (k)(3) of the NPRM is contradictory. Paragraph (k)(1)(v) of the NPRM applies only to the inspection, while paragraph (k)(3) of the NPRM applies to the repair. Similarly, paragraph (k)(1) of this SNPRM applies only to the inspection, while paragraph (k)(2) of this SNPRM applies to the repair.

The FAA acknowledges Hageland Aviation's comment that intrastate aviation within the state of Alaska will be affected if credit is not given. The FAA has revised paragraph (k) of this SNPRM to provide credit for most airplane models that have installed the service kit. Additionally, paragraph (f), ''Compliance,'' of both the NPRM and the SNPRM states compliance is required ''unless already done,'' which allows credit for any AD action completed before the effective date of the AD. Therefore, the FAA is giving credit for previous actions.

Requests To Change the Costs of Compliance

AOPA, Urban Moore, Duane Taylor, Ely Cyrus, Hageland Aviation, Stephen Greenwood, Neal Bachman, Howard Nelson, an anonymous commenter, Paul Gryko, and Richard James requested the FAA update the costs of the service kits. These commenters stated the estimated costs in the NPRM for the installation of the service kits did not represent the current costs of the kits. The commenters also expressed concern that Textron was increasing the prices of the service kits.

The FAA agrees. The FAA has revised the estimated cost of the service kits to account for the known costs.

Urban Moore requested the FAA increase the number of labor hours estimated to complete the repair.

The FAA agrees. The FAA has increased the estimated work-hours to install the service kits from 24 work-hours to 36 work-hours.

An anonymous commenter stated the labor rate of $85 per work-hour is out of date.

The FAA disagrees. The FAA Office of Aviation Policy and Plans provides the labor rate of $85 per work-hour to use when estimating the labor costs of complying with AD requirements.

An anonymous commenter stated the estimated cost in the NPRM should be doubled to account for the cost to repair the doorposts for both wing struts.

The FAA disagrees. The estimated costs in both the NPRM and this

SNPRM already account for repairs on both sides of the airplane.

Request To Correct the Language in the Cost of Compliance for Affected Products

An anonymous commenter noted an error in the estimated costs and stated that the Cost of Compliance section incorrectly refers to 2,928 engines instead of the correct number of airplanes.

The FAA disagrees. The Cost of Compliance section in the NPRM estimates that the proposed AD would affect 14,653 airplanes of U.S. registry; it does not refer to the number of affected engines. The FAA has not changed this proposed AD based on this comment.

Request To Change the Manufacturer Contact Information

Textron requested the FAA change the internet contact information for contacting the manufacturer to *https://support.cessna.com*.

The FAA agrees. The FAA has updated the contact information accordingly.

Request for Docket Correction

Stephen Greenwood noted that in the NPRM the docket number is incorrectly listed as FAA–2017–0049 instead of FAA–2018–0049. The FAA infers that the commenter is requesting that the FAA correct the docket number.

The FAA agrees. The FAA published a proposed rule; correction because of the docket number error in the NPRM on February 13, 2018 (83 FR 6136). This SNPRM references the correct docket number.

Request To Extend the Comment Period

Howard Nelson stated that after the proposed AD is updated with the correct costs for the repair kit, the FAA should extend the comment period.

The FAA agrees. The FAA has updated the estimated cost of the repair service kit and has made other changes that increase the burden on the operators. Therefore, the FAA is issuing this SNPRM to allow further comment on these changes.

Other Differences Between the NPRM and This SNPRM

Table 1 to paragraph (c) of this SNPRM contains changes to some of the model designations listed in the applicability in order to match the models as they are listed in the type certificate data sheet. Where the NPRM referred to ''P206/TP206,'' ''U206/TU206,'' and ''207/T207,'' series of airplanes, this SNPRM identifies the following model designations: P206, P206A, P206B, P206C, P206D, P206E, TP206A, TP206B, TP206C, TP206D, TP206E, U206, U206A, U206B, U206C, U206D, U206E, U206F, U206G, TU206A, TU206B, TU206C, TU206D, TU206E, TU206F, TU206G, 207, 207A, T207, and T207A.

The Model ''F182RG'' listed in Table 1 to paragraph (c) of the NPRM was based on the model designation specified in the service information. Table 1 to paragraph (c) of this SNPRM lists ''Model FR182,'' which is the correct model designation as it is listed in the type certificate data sheet for that model.

This SNPRM also clarifies the affected serial numbers listed in table 1 to paragraph (c) of the NPRM. Where the table to paragraph (c) of this SNPRM identifies an affected serial number range that includes all eligible serial numbers for a given model, the FAA has instead specified ''All serial numbers'' in this SNPRM.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Cessna Single Engine Service Bulletin SEB 95–19, dated December 29, 1995 (SEB 95–19); and Cessna Single Engine Service Bulletin SEB 93–5, Revision 2, dated May 29, 2019 (SEB 93–5R2). For the applicable model airplanes, the service information contains procedures for repetitively inspecting the lower area of the forward cabin doorposts for cracks and repairing any cracks found by modifying the area with an applicable Cessna service kit.

The FAA also reviewed Cessna Single Engine Service Kit SK207–19A, dated May 29, 2019. The service information contains procedures to reinforce the lower forward doorpost bulkhead and wing strut fitting by adding a doubler and a channel to each forward cabin doorpost bulkhead.

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

Other Related Service Information

The FAA reviewed Cessna Single Engine Service Kit SK172–147, dated December 29, 1995. This service kit provides instructions to add a channel to each forward cabin doorpost bulkhead. The FAA also reviewed Cessna Single Engine Service Kit SK182–115, dated December 29, 1995; Cessna Single Engine Service Kit SK206–42D, dated May 29, 2019; and Cessna Single Engine Service Kit SK210–156, dated December 29, 1995. For the applicable model airplanes, these service kits provide instructions to add a doubler and a channel to each forward cabin doorpost bulkhead.

FAA's Determination

The FAA is proposing this AD because the FAA evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design. Certain changes described above expand the scope of the NPRM. As a result, the FAA has determined that it is necessary to reopen the comment period to provide additional opportunity for the public to comment on this SNPRM.

Proposed Requirements of This SNPRM

This SNPRM would require repetitively inspecting the lower area of the forward cabin doorposts for cracks and repairing any cracks found by modifying the area with the applicable Cessna service kit.

Costs of Compliance

The FAA estimates that this proposed AD would affect 14,653 airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspect the lower area of the forward cabin doorposts for cracks.	1.5 work-hours × $85 per hour = $127.50	Not applicable	$127.50	$1,868,257.50
Reporting requirement	1 work-hour × $85 per hour = $85	Not applicable	85	1,245,505

The FAA estimates the following costs to do any necessary repairs that would be required based on the results of the proposed inspection. Reference the applicable Cessna single engine service bulletin for kit applicability. The FAA has no way of determining the number of airplanes that might need this repair:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Install Cessna Single-Engine Service Kit SK172–147	36 work-hours × $85 per hour = $3,060	$3,415	$6,475
Install Cessna Single-Engine Service Kit SK182–115	36 work-hours × 85 per hour = 3,060	7,490	10,550
Install Cessna Single-Engine Service Kit SK206–42D	36 work-hours × 85 per hour = 3,060	3,115	6,175
Install Cessna Single-Engine Service Kit SK207–19A	36 work-hours × 85 per hour = 3,060	4,957	8,017
Install Cessna Single-Engine Service Kit SK210–156	36 work-hours × 85 per hour = 3,060	7,020	10,080

Paperwork Reduction Act

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Information Collection Clearance Officer, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177–1524.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. 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.

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

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have 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.

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Textron Aviation Inc.: Docket No. FAA–2018–0049; Product Identifier 2017–CE–031–AD.

(a) Comments Due Date

The FAA must receive comments by July 13, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the following Textron Aviation Inc. (type certificate previously held by Cessna Aircraft Company) model airplanes, certificated in any category:

TABLE 1 TO PARAGRAPH (C)—AFFECTED MODELS AND SERIAL NUMBERS

Model	Serial Nos.
172N	17272885 through 17274009 inclusive.
172P	All serial numbers.
172Q	17275869, 17275927 through 17275934 inclusive, 17275952, 17275959, 17275960, 17275962, 17275964, 17275965, 17275967, 17275968, 17275969, 17275971, 17275992, 17275999, 17276002, 17276005, 17276029, 17276032, 17276042, 17276045, 17276051, 17276052, 17276054, 17276101, 17276109, 17276140, 17276147, 17276188, and 17276211.
172RG	All serial numbers.
F172N	F17201910 through F17202039 inclusive.
F172P	All serial numbers.

TABLE 1 TO PARAGRAPH (C)—AFFECTED MODELS AND SERIAL NUMBERS—Continued

Model	Serial Nos.
FR172K	FR17200656 through FR17200675 inclusive.
R172K	R1723200 through R1723454 inclusive.
182E	All serial numbers.
182F	All serial numbers.
182G	All serial numbers.
182H	All serial numbers.
182J	All serial numbers.
182K	All serial numbers.
182L	All serial numbers.
182M	All serial numbers.
182N	All serial numbers.
182P	All serial numbers.
182Q	All serial numbers.
182R	All serial numbers.
T182	All serial numbers.
F182P	All serial numbers.
F182Q	All serial numbers.
FR182	All serial numbers.
R182	R18200002 through R18200583 inclusive.
R182 and TR182	R18200001 and R18200584 through R18202039 inclusive.
206	All serial numbers.
P206, P206A, P206B, P206C, P206D, P206E, TP206A, TP206B, TP206C, TP206D, and TP206E.	All serial numbers.
U206, U206A, U206B, U206C, U206D, U206E, U206F, U206G, TU206A, TU206B, TU206C, TU206D, TU206E, TU206F, and TU206G.	All serial numbers.
207, 207A, T207, and T207A	All serial numbers.
210–5 (205)	All serial numbers.
210–5A (205A)	All serial numbers.
210B	All serial numbers.
210C	All serial numbers.
210D	All serial numbers.
210E	All serial numbers.
210F	All serial numbers.
T210F	All serial numbers.

(d) Subject

Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by a report of cracks found in the lower area of the forward cabin doorpost bulkhead. The FAA is issuing this AD to detect and address cracking of the wing strut attach point. The unsafe condition, if not addressed, could result in failure of the wing in operation, which could result in loss of control of the airplane.

(f) Compliance

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

(g) Initial Inspections

(1) For airplanes without a lower forward doorpost bulkhead and wing strut fitting reinforcement service kit (service kit) installed in accordance with Cessna Single Engine Service Bulletin SEB95–19, dated December 29, 1995 (SEB95–19), or Cessna Single Engine Service Bulletin SEB93–5, Revision 2, dated May 29, 2019 (SEB93–5R2): At the applicable compliance time specified in paragraph (g)(1)(i) or (ii) of this AD, do a visual inspection of the lower forward doorpost at the strut attach fitting for cracks in accordance with steps 1.A., 1.B., 1.C., and 1.B. (the step following step 1.C.) of the Accomplishment Instructions in SEB95–19; or steps 1.A. and 1.B. of the Accomplishment Instructions in SEB93–5R2; as applicable to your model airplane.

(i) For airplanes that have accumulated less than 4,000 hours time-in-service (TIS) as of the effective date of this AD: Initially inspect prior to the accumulation of 4,000 hours TIS or within the next 200 hours TIS after the effective date of this AD, whichever occurs later.

(ii) For airplanes that have accumulated 4,000 or more hours TIS as of the effective date of this AD: Initially inspect within 200 hours TIS after the effective date of this AD or within 12 calendar months after the effective date of this AD, whichever occurs first.

(2) For airplanes with a service kit installed in accordance with SEB95–19 or SEB93–5R2: At the later of the times specified in paragraphs (g)(2)(i) and (ii) of this AD, do a visual inspection of the lower forward doorpost at the strut attach fitting for cracks in accordance with steps 1.A., 1.B., 1.C., and 1.B. (the step following step 1.C.) of the Accomplishment Instructions in SEB95–19; or steps 1.A. and 1.B. of the Accomplishment Instructions in SEB93–5R2; as applicable to your model airplane. Do not remove the installed service kit; instead, inspect for cracking that extends beyond the modified parts.

(i) At the applicable time specified in paragraph (g)(1)(i) or (ii) of this AD.

(ii) Within 1,000 hours TIS or 36 calendar months, whichever occurs first, since installing the service kit.

(h) Repetitive Inspections

(1) If no cracks are found during the initial inspection required by paragraph (g)(1) or (2) of this AD, thereafter repeat the inspection at intervals not to exceed 36 calendar months or 1,000 hours TIS, whichever occurs first from the last inspection, as long as no cracks are found.

(2) If cracks are found during any inspection required by paragraph (g)(1) or (h)(1) of this AD, do the inspection specified in paragraph (g)(2) of this AD within 36 calendar months or 1,000 hours TIS, whichever occurs first after installing the service kit required by paragraph (i)(1) of this AD. Thereafter, repeat the inspection at intervals not to exceed 36 calendar months or 1,000 hours TIS, whichever occurs first from the last inspection, as long as no additional cracks are found.

(i) Corrective Actions

(1) If cracks are found during any inspection required by paragraph (g)(1) or paragraph (h)(1) of this AD, before further

flight, install a service kit in accordance with step 1.D. of the Accomplishment Instructions in SEB95–19; or step 1.C. of the Accomplishment Instructions in SEB93–5R2; as applicable to your model airplane.

(2) If cracks are found during any inspection required by paragraph (g)(2) or (h)(2) of this AD, before further flight, repair the area using a method approved by the Manager, Wichita ACO Branch, FAA. For a repair method to be approved by the Manager, Wichita ACO Branch as required by this paragraph, the Manager's approval letter must specifically refer to this AD. You may use the contact information in paragraph (n)(1) of this AD to obtain FAA approval of your repair method.

(j) Reporting Requirement

Within 30 days after the effective date of this AD, or within 30 days after completing the initial inspection required by paragraph (g) of this AD, whichever occurs later, report the findings of the initial inspection (regardless if cracks were found or not) to the FAA at *Wichita-COS@faa.gov*. Thereafter, within 30 days after completing each repetitive inspection required by paragraph (h) of this AD, if any crack was found, report the crack findings to the FAA at *Wichita-COS@faa.gov*. Include in your reports the following information:

(1) Name and address of the owner;

(2) Date of the inspection;

(3) Name, address, telephone number, and email address of the person submitting the report;

(4) Airplane serial number and total hours TIS on the airplane at the time of the inspection; and

(5) If any crack was found during the inspection, provide detailed crack information as specified below:

(i) A sketch or picture detailing the crack location;

(ii) Measured length of the crack(s) found;

(iii) Installation of a Cessna service kit or any other kit or repair before the inspection; and

(iv) Installation of any supplemental type certificates (STCs), alterations, repairs, or field approvals affecting the area of concern or affecting gross weight.

(k) Credit for Previous Actions

(1) You may take credit for the initial inspection required by paragraph (g) of this AD if you performed the inspection before the effective date of this AD using Cessna Single Engine Service Bulletin SEB93–5, dated March 26, 1993; or Cessna Single Engine Service Bulletin SEB93–5, Revision 1, dated September 8, 1995.

(2) You may take credit for the installation required by paragraph (i)(1) of this AD as follows.

(i) For Model 207, T207, 207A, and T207A airplanes with a service kit installed using SK206–42, SK206–42A, SK206–42B, or SK206–42C: You may take credit for the installation if done before the effective date of this AD using Cessna Single Engine Service Bulletin SEB93–5, dated March 26, 1993, or Cessna Single Engine Service Bulletin SEB93–5, Revision 1, dated September 8, 1995; if the reinforcement of the lower forward doorpost bulkhead and wing strut fitting specified in Cessna Single Engine Service Kit SK207–19A, dated May 29, 2019, is also accomplished within 200 hours TIS after the effective date of this AD.

(ii) For all other models: You may take credit for the installation if done before the effective date of this AD using Cessna Single Engine Service Bulletin SEB 93–5, dated March 26, 1993; or Cessna Single Engine Service Bulletin SEB 93–5, Revision 1, dated September 8, 1995.

(l) Paperwork Reduction Act Burden Statement

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120–0056. Public reporting for this collection of information is estimated to be approximately 1 hour per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW, Washington, DC 20591, Attn: Information Collection Clearance Officer, AES–200.

(m) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Wichita ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (n)(1) of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(n) Related Information

(1) For more information about this AD, contact Bobbie Kroetch, Aerospace Engineer, Wichita ACO Branch, 1801 Airport Road, Room 100, Wichita, Kansas 67209; telephone: (316) 946–4155; fax: (316) 946–4107; email: *bobbie.kroetch@faa.gov* or *Wichita-COS@faa.gov*.

(2) For service information identified in this AD, contact Textron Aviation Inc., Textron Aviation Customer Service, One Cessna Blvd., Wichita, Kansas 67215; telephone: (316) 517–5800; email: *customercare@txtav.com;* internet: *https://support.cessna.com*. You may review this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued on May 21, 2020.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–11340 Filed 5–28–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2020–0248]

RIN 1625–AA00

Safety Zone; Apra Outer Harbor, Naval Base Guam

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a temporary safety zone for certain waters of Apra Outer Harbor. This action is necessary to provide for the safety of life on these navigable waters near Polaris Point, Guam, during a fireworks display on July 4, 2020. This proposed rulemaking would prohibit persons and vessels from entering the safety zone unless authorized by the Captain of the Port Guam (COTP) 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 June 29, 2020.

ADDRESSES: You may submit comments identified by docket number USCG–2020–0248 using the Federal eRulemaking 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 Chief Robert Davis, Sector Guam, U.S. Coast Guard; telephone 671–355–4866, email *wwmguam@uscg.mil*.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
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

Navy MWR will be conducting a fireworks display between 6 p.m. and 9 p.m. on July 4, 2020. The fireworks are to be launched from a barge in Apra Outer Harbor, approximately 300-yards west of Polaris Point, Guam. Hazards from firework display include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. The COTP has determined that potential hazards associated with the fireworks to be used in this display would be a safety concern for anyone within a 190-yard radius of the barge.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters within a 190-yard radius of the fireworks barge before, during, and after 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 to establish a safety zone from 6 p.m. to 9 p.m. on July 4, 2020. The safety zone would cover all navigable waters within 190 yards of a barge in Apra Outer Harbor located approximately 300 yards west of Polaris Point, Guam. The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the scheduled 6 p.m. to 9 p.m. fireworks display. No vessel or person would be permitted to enter the safety zone 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. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. 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), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, location, duration, and time-of-year of the safety zone. Vessel traffic will be able to safely transit around this safety zone, which will impact a small designated area of the Apra Outer Harbor for 3 hours. The safety zone will impact a small section of the main channel for Navy traffic, however Navy traffic will be able to transit around the area safely. This is also the main traffic area for the Marianas Yacht Club in Sasa Bay. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule allows vessels to seek 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 safety zone 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 safety zone lasting no more than 3 hours that would prohibit entry within 190 yards of a fireworks barge. Normally such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A preliminary Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble. 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.

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov*. If your material cannot be submitted using *https://www.regulations.gov,* call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 165

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

For the reasons discussed in the preamble, the Coast Guard is proposing to amend 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T05–0248 to read as follows:

165. T05–0248 Safety Zone; Apra Outer Harbor, Naval Base Guam.

(a) *Location.* The following areas, within the Captain of the Port Guam (COTP) Zone (See 33 CFR 3.70–15), all navigable waters on the surface and below the surface within 190 yards of the fireworks barge for the 4th of July celebrations at Polaris Point, Naval Base Guam. The following position 13 degrees 26 minutes 44.76 seconds N Latitude, 144 degrees 39 minutes 59.16 seconds E Longitude is to be used as a guide to the location of the barge.

(b) *Effective Dates.* This rule is effective from 6 p.m. through 9 p.m. on July 4, 2020.

(c) *Enforcement.* All persons are required to comply with the general regulations governing safety zones found in § 165.23. Entry into or remaining in this zone is prohibited unless authorized by the Coast Guard Captain of the Port Guam. Persons desiring to transit the area of the safety zone must first request authorization from the Captain of the Port Guam or his designated representative. To seek permission to transit the area, the Captain of the Port Guam and his designated representatives can be contacted at telephone number (671) 355–4821 or on Marine Band Radio, VHF–FM channel 16 (156.8 MHz). Any Coast Guard commissioned, warrant, or petty officer, and any other COTP representative permitted by law, may enforce this temporary safety zone.

(d) *Waiver.* The COTP may waive any of the requirements of this rule for any person, vessel, or class of vessel upon finding that application of the safety zone is unnecessary or impractical for the purpose of maritime security.

(g) *Penalties.* Vessels or persons violating this rule are subject to the penalties set forth in 46 U.S.C. 70036 and 46 U.S.C. 70052.

Dated: May 19, 2020.

Christopher M. Chase,

Captain, U.S. Coast Guard, Captain of the Port, Guam.

[FR Doc. 2020–11062 Filed 5–28–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF EDUCATION

34 CFR Chapter III

[Docket ID ED–2020–OSERS–0014]

Proposed Priorities, Requirements, and Selection Criteria—Technical Assistance and Dissemination To Improve Services and Results for Children With Disabilities—The Individuals With Disabilities Education Act (IDEA) Paperwork Reduction Planning and Implementation Program

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Proposed priorities, requirements, and selection criteria.

SUMMARY: The Department of Education (Department) proposes priorities, requirements, and selection criteria for the IDEA Paperwork Reduction Planning and Implementation Program, Catalog of Federal Domestic Assistance (CFDA) number 84.326F. The Department may select as many as 15 States to receive support in planning for and implementing waivers of statutory requirements of, or regulatory requirements relating to, IDEA Part B to reduce excessive paperwork and noninstructional time burdens that do not assist in improving educational and functional results for children with disabilities. The Department may use the priorities, requirements, and selection criteria in this document for competitions in fiscal year (FY) 2020 and later years. The IDEA Paperwork Reduction Planning and Implementation Program focuses on an identified national need to reduce the paperwork burden associated with the requirements of IDEA Part B while preserving the rights of children with disabilities and promoting academic achievement.

DATES: We must receive your comments on or before June 29, 2020.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* to submit your comments electronically. Information on using *Regulations.gov,* including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under ''Help.''
- *Postal Mail, Commercial Delivery, or Hand Delivery:* If you mail or deliver your comments about the proposed priorities, requirements, and selection criteria, address them to David Egnor, U.S. Department of Education, 400 Maryland Avenue SW, Room 5163, Potomac Center Plaza, Washington, DC 20202–5076.

Privacy Note: The Department's policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov*. Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: David Egnor, U.S. Department of Education, 400 Maryland Avenue SW, Room 5163, Potomac Center Plaza, Washington, DC 20202–5076. Telephone: (202) 245–7334. Email: *David.Egnor@ed.gov*.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Invitation to Comment: We invite you to submit comments regarding the proposed priorities, requirements, and selection criteria. To ensure that your comments have maximum effect in developing the final priorities, requirements, and selection criteria, we urge you to identify clearly the specific section of the proposed priorities, requirements, or selection criterion that each comment addresses.

We are particularly interested in comments about whether the proposed priorities, requirements, and selection criteria would be challenging for new applicants to meet and, if so, how the proposed priorities, requirements, and selection criteria could be revised to address potential challenges and reduce burden.

Directed Questions:

1. We invite specific public comment on the extent to which the activities in these priorities, requirements, and selection criteria are appropriate for States and whether there are alternatives that would accomplish the same purposes with less burden for States.

2. Although the Department reserves its discretion to establish award sizes, we further invite public input on the appropriate size of awards under these priorities.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866, 13563, and 13771 and their overall requirement of reducing regulatory burden that might result from the proposed priorities, requirements, and selection criteria. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about the proposed priorities, requirements, and selection criteria by accessing *Regulations.gov*. You may also inspect the comments in person in Room 5163, 550 12th Street SW, Potomac Center Plaza, Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Eastern Time, Monday through Friday of each week except Federal holidays. Please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request, we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for the proposed priorities, requirements, and selection criteria. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Purpose of Program: The purpose of the Technical Assistance and Dissemination to Improve Services and Results for Children with Disabilities program is to promote academic achievement and to improve results for children with disabilities by providing technical assistance (TA), supporting model demonstration projects, disseminating useful information, and implementing activities that are supported by scientifically-based research.

Program Authority: 20 U.S.C. 1408 and 1463.

Proposed Priorities

Background: The Secretary believes that all students should be given the opportunity to succeed and that their success should be the primary focus of everyone in the educational system. When teachers, related services providers, and administrators who serve children with disabilities spend time completing unnecessary paperwork, their ability to prioritize and focus on improving outcomes for children with disabilities is hampered.

In the 2004 reauthorization of IDEA, Congress recognized that some Federal IDEA Part B requirements could create excessive paperwork and noninstructional time burdens on special education teachers, related services providers, and State and local administrators, thus diverting time and resources away from instruction and other activities that would improve educational and functional results for children with disabilities.

As such, under section 609 of IDEA, Congress gave the Department limited authority to grant waivers of certain requirements of IDEA Part B. Waivers may be granted to not more than 15 States and for a period not to exceed 4 years. Further, the Secretary may not waive any statutory or regulatory provisions relating to applicable civil rights requirements or allow States or local educational agencies to waive procedural safeguards under section 615 of IDEA, and waivers may not affect the right of a child with a disability to receive a free appropriate public education (FAPE) under IDEA Part B. In short, States' waiver proposals must preserve the fundamental rights of children with disabilities under IDEA.[1] In addition, States have always had the authority, within the constraints of State law, to change or waive State requirements that exceed IDEA statutory and regulatory requirements in order to reduce administrative burden.

Under section 609 of IDEA, the waivers must be based upon proposals submitted by States. In a document

[1] For any State that receives a waiver of Federal IDEA Part B requirements, the Secretary will terminate the waiver if the Secretary determines that the State failed to appropriately implement its waiver, or the Secretary determines the State needs assistance in implementing IDEA requirements and the waiver has contributed to or caused such need for assistance. The Secretary will also terminate the waiver if the Secretary determines the State needs intervention in implementing IDEA requirements, or needs substantial intervention in implementing IDEA requirements.

published elsewhere in this issue of the **Federal Register**, the Department is proposing requirements for States to obtain waivers under section 609 of IDEA (the IDEA Paperwork Reduction Waivers). We invite the public to review that document in conjunction with this one and identify any potential inconsistencies or implementation issues that may arise.

The Department also recognizes that the implementation and evaluation of waivers granted under section 609 of IDEA may require additional Federal support. As such, the Department proposes these priorities, requirements, and selection criteria to make funding available for planning for, and then implementing, waivers of requirements under section 609 of IDEA to reduce excessive paperwork and non-instructional time burdens and thus improve educational and functional results for children with disabilities.

States may apply for a planning grant, an implementation grant, or both.

Proposed Priority 1: The Individuals with Disabilities Education Act (IDEA) Paperwork Reduction Planning and Implementation Program—Planning Grants.

The Department seeks to make awards under section 609 of IDEA to State educational agencies (SEAs) to assist them in identifying excessive paperwork and noninstructional time burdens on special education teachers, related services providers, and State and local administrators that do not assist in improving educational and functional results for children with disabilities (hereafter in the priority, ''administrative burdens'') and developing comprehensive plans to reduce them. These activities include conducting a comprehensive review of local, State, and Federal IDEA Part B requirements that lead to administrative burdens, as well as, at the discretion of the State, preparing IDEA Paperwork Reduction Waivers for submission to the Department.

Planning projects funded by the Department must achieve, at a minimum, the following expected outcomes—

- Identification of the particular sources and effects of administrative burdens on special education and other teachers, related services providers, and State and local administrators under IDEA Part B; and
- A plan to reduce these administrative burdens.

Under this priority, applicants must propose projects that meet the following programmatic requirements:

(a) The project must meaningfully consult a diverse group of stakeholders on an ongoing basis to support the goals and objectives of the project. Such a group must include, at a minimum, representatives of the following groups:

(i) Special education teachers and related services providers.

(ii) Local special education administrators.

(iii) Individuals with disabilities.

(iv) Parents of children with disabilities, as defined in IDEA section 602(23).

(v) The State Advisory Panel.

(b) The project must prepare a plan that—

(i) Identifies the State and local statutory and regulatory requirements or policies, procedures, and practices that exceed IDEA Part B statutory and regulatory requirements and were considered for revision;

(ii) Describes the range of options available to the State in reducing administrative burdens, including any limitations on those options (*e.g.,* statutory or regulatory requirements, judicial precedent);

(iii) Establishes clear and achievable timelines for reducing administrative burdens;

(iv) Identifies the anticipated benefits of any potential reforms, including likely beneficiaries, and the magnitude and scope of anticipated benefits such as reductions in administrative burden hours and potential increases in the time and resources available for instruction and other activities intended to improve educational and functional results for children with disabilities;

(v) Identifies any Federal IDEA Part B statutory or regulatory requirements for which a waiver may be sought under section 609 of IDEA; and

(vii) Describes the procedures the State will use to ensure that any waiver that may be sought in accordance with section 609 of IDEA will not—

(A) Waive any statutory requirements of, or regulatory requirements relating to, applicable civil rights requirements or procedural safeguards under section 615 of IDEA; or

(B) Affect the right of a child with a disability to receive FAPE under IDEA Part B.

To be considered for funding under this priority, applicants must also meet the following application requirements. Each applicant must—

(a) Demonstrate, in the narrative portion of the application under ''Need for the project,'' how the proposed project will identify administrative burdens. To meet this requirement, the applicant must describe what it believes to be—

(1) The approximate current magnitude and scope of the administrative burdens to be addressed;

(2) The approximate current number of special education teachers, related services providers, and State and local administrators affected by those burdens and the number of children with disabilities that they serve; and

(3) The approximate current costs and benefits of those burdens on special education teachers, related services providers, State and local administrators, and children with disabilities (*e.g.,* teacher retention, planning time, transparency for families);

(b) Demonstrate, in the narrative portion of the application under ''Significance'' how the proposed planning project will—

(1) Develop a plan to reduce administrative burdens and produce meaningful and sustained change at the State or local level; and

(2) Develop proposals for changes to, or waivers of, specific requirements, policies, procedures, or practices that will reduce administrative burdens in order to increase the time and resources available for instruction and other activities aimed at improving educational and functional results for children with disabilities;

(c) Demonstrate, in the narrative section of the application under ''Quality of the project design,'' how the proposed project will—

(1) Meet the consultation requirements in paragraph (a) of the programmatic requirements of this priority, including, but not limited to, a proposed timeline for the consultation process, including a description of the methods of consultation (*e.g.,* in-person meetings, conference calls, emails);

(2) Identify local, State, or Federal IDEA Part B requirements, policies, procedures, or practices that may generate administrative burdens and may be reviewed by the project, including any proposed criteria for that review (*e.g.,* frequency, complexity, number of staff affected, number of families affected);

(3) Assess the extent to which specific sources of administrative burdens may affect educational and functional results for children with disabilities; and

(4) Produce and make publicly available a plan that meets the requirements in paragraph (b) under the programmatic requirements of this priority and provide an opportunity for stakeholders enumerated in paragraph (a) of the programmatic requirements of this priority to comment on the plan; and

(d) Demonstrate, in the narrative section of the application under ''Quality of the management plan,'' how—(1) The proposed management

plan will ensure that the project's intended outcomes will be achieved on time and within budget. To address this requirement, the applicant must describe—

(i) Clearly defined responsibilities for key project personnel, consultants, and subcontractors, as applicable; and

(ii) Timelines and milestones for accomplishing the project tasks, including the publication of the final plan on the State's website within three months of the close of the project period;

(2) Key project personnel and any consultants and subcontractors will be allocated and how these allocations are appropriate and adequate to achieve the project's intended outcomes; and

(3) The proposed project will benefit from a diversity of perspectives, including those of families, educators, TA providers, researchers, and policymakers, among others, in its development and operation.

Proposed Priority 2: The Individuals with Disabilities Education Act (IDEA) Paperwork Reduction Planning and Implementation Program—Implementation Grants.

Implementation grants would provide funds for States to implement comprehensive plans to reduce administrative burdens submitted by the State and approved by the Secretary under section 609 of IDEA. This includes costs associated with developing products or materials that are part of comprehensive plans, such as creating information technology systems to automate paperwork, or creating new, streamlined paperwork to replace more time-consuming paperwork.

To be considered for funding under this priority, an applicant must meet the following application requirements. Each applicant must—

(a) Demonstrate, in the narrative section of the application under ''Quality of the project design,'' how the proposed project will—

(1) Disseminate information about changes in processes, practices, and procedures necessary to reduce administrative burdens to all special education teachers, related services providers, and State and local administrators affected by the State's waiver under section 609 of IDEA (hereafter ''affected staff''), including—

(i) The modes of communication the project will use;

(ii) The frequency of communication; and

(iii) The content of such communications;

(2) Support the training of all affected staff regarding changes in processes, practices and procedures necessary to reduce administrative burdens, including a description of the project's intended means of providing this training;

(b) Demonstrate, in the narrative section of the application under ''Quality of the management plan,'' how—

(1) The proposed management plan will ensure that the project's intended outcomes will be achieved on time and within budget. To address this requirement, the applicant must describe—

(i) Clearly defined responsibilities for key project personnel, consultants, and subcontractors, as applicable; and

(ii) Timelines and milestones for accomplishing the project tasks;

(2) Key project personnel and any consultants and subcontractors will be allocated and how these allocations are appropriate and adequate to achieve the project's intended outcomes; and

(3) The proposed project will benefit from a diversity of perspectives, including those of families, educators, TA providers, researchers, and policymakers, among others, in its development and operation; and

(c) Include, in the narrative section of the application under ''Quality of the project evaluation,'' an evaluation plan for the implementation project. The evaluation plan must—

(1) Articulate formative and summative evaluation questions for evaluating important processes and outcomes, including whether, and how effectively, the waiver—

(i) Reduces paperwork burden on teachers, principals, administrators, and related services providers;

(ii) Reduces non-instructional time spent by teachers in complying with IDEA Part B;

(iii) Enhances longer-term educational planning;

(iv) Improves positive outcomes, including educational and functional results, for children with disabilities;

(v) Promotes collaboration between individualized education program (IEP) Team members; and

(vi) Ensures satisfaction of family members of children with disabilities and teachers, principals, administrators, and related service providers;

(2) Describe how progress in, and fidelity of, implementation, as well as project outcomes, will be measured to answer the evaluation questions; specify the measures and associated instruments or sources for data appropriate to the evaluation questions; and include information regarding reliability and validity of measures where appropriate;

(3) Describe strategies for analyzing data and how data collected as part of this plan will be used to inform and improve service delivery over the course of the project and to refine the proposed implementation project and evaluation plan, including subsequent data collection;

(4) Provide a timeline for conducting the evaluation and include staff assignments for completing the evaluation; and

(5) Dedicate sufficient funds in each budget year to cover the costs of developing, refining, and implementing the evaluation plan.

Proposed Requirements

The Department proposes the following requirements for these priorities. We may apply one or more of these requirements in any year in which the program is in effect.

Funding Eligibility Requirements:

(a) In order to be eligible for an implementation grant an applicant must already have a waiver under section 609 of IDEA approved by the Secretary.

(b) For an applicant that receives a grant under proposed priority 1—

(1) That does not submit a waiver proposal to the Secretary under section 609 of the IDEA within 12 months of the start of the project period, the grant will end after 12 months without opportunity for extension;

(2) That submits a waiver proposal to the Secretary under section 609 of the IDEA within 12 months of the start of the project period, the project period will be automatically extended for a period, not to exceed six months, during which the Secretary will consider the proposal.

(i) While a State's waiver proposal is under review, grantees may continue to access available remaining funds to conduct one or more of the following planning grant activities:

(A) Responding to possible questions from the Department regarding the State's proposal to obtain a waiver under section 609 of IDEA and the IDEA Paperwork Reduction Waivers.

(B) Continuing to develop, or implement, planned activities to reduce administrative burdens.

(ii) If the Secretary approves the State's IDEA paperwork reduction waiver under section 609 of IDEA, the grantee may continue to access available remaining funds to ensure continuity of the project while applying for an implementation award under Priority 2 to implement and evaluate the IDEA Paperwork Reduction Waivers.

(iii) If the Secretary denies the State an IDEA paperwork reduction waiver under section 609 of IDEA, the project period will end no more than 30 days after the State's receipt of the Secretary's

decision, without opportunity for extension.

Proposed Selection Criteria

The Department proposes the following selection criteria for evaluating applications under this program. We may apply one or more of these criteria in any year in which this program is in effect.

(a) *Significance.*

(1) The Secretary considers the significance of the proposed project.

(2) In determining the significance of the proposed project, the Secretary considers the likelihood that the proposed project will reduce administrative burdens and increase the time and resources available for instruction and other activities aimed at improving educational and functional results for children with disabilities.

(b) *Quality of the project design.*

(1) The Secretary considers the quality of the design of the proposed project.

(2) In determining the quality of the design of the proposed project, the Secretary considers the following factors:

(i) The extent to which the design of the proposed project will successfully reduce administrative burdens and increase the time and resources available for instruction and other activities aimed at improving educational and functional results for children with disabilities.

(ii) The extent to which the proposed project encourages and is responsive to consumer involvement, including parental involvement.

(iii) The extent to which the goals, objectives, and outcomes to be achieved by the proposed project are clearly specified and measurable.

(iv) The extent to which the design for implementing and evaluating the proposed project will result in information to guide possible replication of project activities or strategies, including information about the effectiveness of the approach or strategies employed by the project.

(c) *Quality of the management plan.*

(1) The Secretary considers the quality of the management plan for the proposed project.

(2) In determining the quality of the management plan for the proposed project, the Secretary considers how the applicant will ensure that a diversity of perspectives is brought to bear in the operation of the proposed project, including those of parents, teachers, related services providers, school administrators, and others, as appropriate.

Final Priorities, Requirements, and Selection Criteria

We will announce the final priorities, requirements, and selection criteria in a document in the **Federal Register**. We will determine the final priorities, requirements, and selection criteria after considering public comments and other information available to the Department. This document does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This document does *not* solicit applications. In any year in which we choose to use these proposed priorities, requirements, and selection criteria, we invite applications through a notice in the **Federal Register**.

Executive Orders 12866, 13563, and 13771

Regulatory Impact Analysis

Under Executive Order 12866, the Office of Management and Budget (OMB) determines whether this regulatory action is ''significant'' and, therefore, subject to the requirements of the Executive order and subject to review by OMB. Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action likely to result in a rule that may—

(1) Have an annual effect on the economy of $100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities in a material way (also referred to as an ''economically significant'' rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

OMB has determined that this proposed regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

Under Executive Order 13771, for each new rule that the Department proposes for notice and comment or otherwise promulgates that is a significant regulatory action under Executive Order 12866, and that imposes total costs greater than zero, it must identify two deregulatory actions. For FY 2020, any new incremental costs associated with a new regulation must be fully offset by the elimination of existing costs through deregulatory actions. Because the proposed regulatory action is not significant, the requirements of Executive Order 13771 do not apply.

We have also reviewed this proposed regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency—

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account—among other things and to the extent practicable—the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives—such as user fees or marketable permits—to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency ''to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.'' The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include ''identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes.''

We are issuing these proposed priorities, requirements, and selection criteria based on a reasoned determination that the benefits would justify the costs. In choosing among alternative regulatory approaches, we selected those approaches that would maximize net benefits. Based on the analysis that follows, the Department believes that this regulatory action is consistent with the principles in

Executive Order 13563. In summary, the potential costs associated with this final priority would be minimal, while the potential benefits are significant. The Department believes that this regulatory action does not impose significant costs on eligible entities. Participation in this program is voluntary, and the costs imposed on applicants by this regulatory action will be limited to paperwork burden related to preparing an application. The potential benefits of implementing the program—including improved data integration and improved data quality—would outweigh the costs incurred by applicants, and the costs of carrying out activities associated with the application will be paid for with program funds. For these reasons, we have determined that the costs of implementation will not be excessively burdensome for eligible applicants, including small entities.

We also have determined that this regulatory action would not unduly interfere with State, local, and Tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as necessary for administering the Department's programs and activities.

In addition, we have considered the potential benefits of this regulatory action and have noted these benefits in the background section of this document.

Paperwork Reduction Act of 1995

The proposed priorities, requirements, and selection criteria contain information collection requirements that are approved by OMB under OMB control number 1820–0028; the proposed priorities, requirements, and selection criteria do not affect the currently approved data collection.

Clarity of the Regulations

Executive Order 12866 and the Presidential memorandum ''Plain Language in Government Writing'' require each agency to write regulations that are easy to understand.

The Secretary invites comments on how to make the proposed priorities, requirements, and selection criteria easier to understand, including answers to questions such as the following:

- Are the requirements in the proposed regulations clearly stated?
- Do the proposed regulations contain technical terms or other wording that interferes with their clarity?
- Does the format of the proposed regulations (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce their clarity?
- Would the proposed regulations be easier to understand if we divided them into more (but shorter) sections?
- Could the description of the proposed regulations in the **SUPPLEMENTARY INFORMATION** section of this preamble be more helpful in making the proposed regulations easier to understand? If so, how?
- What else could we do to make the proposed regulations easier to understand?

Regulatory Flexibility Act Certification: The Secretary certifies that this proposed regulatory action would not have a significant economic impact on a substantial number of small entities. The U.S. Small Business Administration (SBA) Size Standards define ''small entities'' as for-profit or nonprofit institutions with total annual revenue below $7,000,000 or, if they are institutions controlled by small governmental jurisdictions (that are comprised of cities, counties, towns, townships, villages, school districts, or special districts), with a population of less than 50,000.

The small entities that this proposed regulatory action would affect are State educational agencies; local educational agencies (LEAs), including charter schools that operate as LEAs under State law; and freely associated States and outlying areas. We believe that the costs imposed on an applicant by the proposed priorities, requirements, and selection criteria would be limited to paperwork burden related to preparing an application and that the benefits of the proposed priorities, requirements, and selection criteria would outweigh any costs incurred by the applicant.

Participation in the Technical Assistance and Dissemination to Improve Services and Results for Children with Disabilities program is voluntary. For this reason, the proposed priorities, requirements, and selection criteria would impose no burden on small entities unless they applied for funding under the program. We expect that in determining whether to apply for Technical Assistance and Dissemination to Improve Services and Results for Children with Disabilities program funds, an eligible entity would evaluate the requirements of preparing an application and any associated costs, and weigh them against the benefits likely to be achieved by receiving a Technical Assistance and Dissemination to Improve Services and Results for Children with Disabilities program grant. An eligible entity would probably apply only if it determines that the likely benefits exceed the costs of preparing an application.

We believe that the proposed priorities, requirements, and selection criteria would not impose any additional burden on a small entity applying for a grant than the entity would face in the absence of the proposed action. That is, the length of the applications those entities would submit in the absence of the proposed regulatory action and the time needed to prepare an application would likely be the same.

This proposed regulatory action would not have a significant economic impact on a small entity once it receives a grant because it would be able to meet the costs of compliance using the funds provided under this program. We invite comments from eligible small entities as to whether they believe this proposed regulatory action would have a significant economic impact on them and, if so, request evidence to support that belief.

Intergovernmental Review: This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov*. At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov*.

Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Mark Schultz,

Commissioner, Rehabilitation Services Administration. Delegated the authority to perform the functions and duties of the Assistant Secretary for the Office of Special Education and Rehabilitative Services.

[FR Doc. 2020–11417 Filed 5–28–20; 8:45 am]

BILLING CODE 4000–01–P

LIBRARY OF CONGRESS

Copyright Royalty Board

37 CFR Part 370

[Docket No. 20–CRB–0007–RM]

Regulation Concerning Proxy Distributions for Unmatched Royalties Deposited During 2010–2018

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Proposed rule.

SUMMARY: The Copyright Royalty Judges are proposing to amend their regulations concerning proxy distributions for unmatched royalties deposited pursuant to statutory license for the period 2010 through 2018.

DATES: Comments are due no later than June 29, 2020.

ADDRESSES: You may submit comments and proposals, identified by docket number 20–CRB–0007–RM, online via eCRB, the Copyright Royalty Board's online electronic filing application, at *https://app.crb.gov/*.

Instructions: All submissions must include a reference to the CRB and this docket number. All submissions will be posted without change to eCRB at *https://app.crb.gov/* including any personal information provided.

Docket: For access to the docket to read submitted background documents or comments, go to eCRB, the Copyright Royalty Board's electronic filing and case management system, at *https://app.crb.gov/,* and search for docket number 20–CRB–0007–RM.

FOR FURTHER INFORMATION CONTACT: Anita Blaine, CRB Program Specialist, by telephone at (202) 707–7658 or email at *crb@loc.gov*.

SUPPLEMENTARY INFORMATION:

Background

The Copyright Act grants copyright owners of sound recordings the exclusive right to perform their works publicly by means of digital audio transmissions subject to certain limitations and exceptions. Among the limitations placed on the performance right for sound recordings is a statutory license that permits certain eligible subscription, nonsubscription, satellite digital audio radio services, and business establishment services to perform those sound recordings publicly by means of digital audio transmissions. 17 U.S.C. 114.

Similarly, copyright owners of sound recordings are granted the exclusive right to make copies of their works subject to certain limitations and exceptions. Among the limitations placed on the reproduction right for sound recordings is a statutory license that permits certain eligible subscription, nonsubscription, satellite digital audio radio services, and business establishment services to make ephemeral copies of those sound recordings to facilitate their digital transmission. 17 U.S.C. 112(e).

Both the section 114 and 112 licenses require services to, among other things, pay royalty fees and to report to copyright owners of sound recordings on the use of their works. Both licenses direct the Copyright Royalty Judges (''Judges'') to determine the royalty rates to be paid, 17 U.S.C. 114(f)(1)(A), (f)(2)(A) and 17 U.S.C. 112(e)(3), and to establish regulations to give copyright owners reasonable notice of the use of their works and create and maintain records of use for delivery to copyright owners. 17 U.S.C. 114(f)(4)(A) and 17 U.S.C. 112(e)(4). The royalty fees collected under the section 114 and 112 licenses, as determined by the Judges, are paid to a central source known as a Collective.[1] 37 CFR 380.2(a). The purpose of the notice and recordkeeping requirement is to ensure that the royalties collected under the statutory licenses are distributed to the correct recipients.

On March 24, 2011, SoundExchange petitioned the Judges to commence a rulemaking proceeding to consider adopting regulations to authorize SoundExchange, when a licensee fails to provide usable reports of use, to use reporting data from certain other licensees (proxy reporting data) as a basis for distributing sound recording royalties deposited by that licensee during the period prior to 2010 to copyright owners and performers. Petition of SoundExchange, Inc. for a Rulemaking to Authorize Use of a Proxy to Distribute Certain Pre-2010 Sound Recording Royalties at 1–2 and n.1, Docket No. RM 2011–5 (March 24, 2011). After notice and comment, the Judges adopted SoundExchange's proposal to use proxy reporting data to permit distribution of royalties collected for the period April 1, 2004, through December 31, 2009, for the public performance of sound recordings by means of digital audio transmissions pursuant to statutory license for those services for which no reports of use were submitted or for which the reports of use were unusable. 76 FR 45695 (Aug. 1, 2011).[2]

On November 20, 2018, SoundExchange requested that the Judges amend the Judges' regulations to authorize SoundExchange to continue to use proxy reporting data to distribute to copyright owners and performers certain sound recording royalties collected by SoundExchange for periods before January 1, 2019, that are otherwise undistributable due to licensees' failure to provide reports of use or their provision of reports of use that are so deficient as to be unusable. Letter from Steven R. Englund, Counsel for SoundExchange, Inc., Docket No. 14–CRB–0005 (RM) (SoundExchange Letter I).[3] SoundExchange stated that it was holding $24 million in royalties for the period 2010 through 2016 and additional royalties for 2017 that are undistributable due to missing or unusable reports of use. SoundExchange Letter I at 1 & n.1.

SoundExchange renewed its request on April 23, 2020. SoundExchange Letter II. In that letter, SoundExchange stated it was holding approximately $32 million in statutory royalties for the period 2010 through 2018 and requested that the Judges authorize SoundExchange to distribute these royalties using the same ''annual/license type methodology'' that the Judges approved in 2011. SoundExchange Letter II at 2, citing 37 CFR 370.3(i), 370.4(f). SoundExchange requested that the Judges change the dates in the current applicable regulations from 2010 to 2019, which would authorize SoundExchange to distribute royalties from the period 2010 through 2018 by using proxy reports of use. SoundExchange Letter II at 2–3.

[1] SoundExchange, Inc., has been the Collective since the inception of the two licenses.

[2] The Copyright Office approved a similar proposal in 2004 covering the 1998 to 2004 period. 69 FR 58261 (Sept. 30, 2004).

[3] SoundExchange submitted its letter further to Docket No. 14–CRB–0005 RM, Notice and Recordkeeping for Use of Sound Recordings Under Statutory License, which is still pending with the Judges. The 2014 petition included, among other proposals, a provision that would authorize SoundExchange to distribute royalties that did not have a useable, matching report of use by a proxy methodology that SoundExchange would develop in its discretion, on an ongoing basis. Letter from Steven R. Englund, Counsel for SoundExchange, Inc. (SoundExchange Letter II) at 2.

In light of SoundExchange's requests, the Judges propose to authorize SoundExchange to continue to use the proxy distribution methodologies in 37 CFR 370.3(i), and 370.4(f) to distribute royalties for the period 2010 through 2018. Although the current regulations use the mandatory ''shall,'' the Judges propose to use the permissive ''may'' to authorize such distributions.

Solicitation of Comments on the Proposed Regulations

The Judges seek comment from interested parties on the Judges' proposal to permit SoundExchange to use a proxy for the distribution of royalties collected under the section 114 and 112 licenses for the period 2010 through 2018. In addition to general comments regarding the proposal, the Judges seek comments on the following areas:

1. SoundExchange has requested that the Judges extend the current regulations that require rather than permit SoundExchange to use a proxy distribution methodology for allocating royalties that SoundExchange cannot match with a report of use. The regulations that the Judges propose would permit but not require SoundExchange to use such a proxy methodology. The Judges seek comment on the propriety of the proposed change regarding SoundExchange's ability to distribute unmatched royalties.

2. Has SoundExchange exhausted all reasonable means to ensure that all undistributed royalties for the period from 2010 through 2018, have been distributed to the party that earned those royalties? If not, what other means could SoundExchange use to facilitate further distributions without resorting to proxy reports of use?

3. Assuming that SoundExchange has exhausted all reasonable means of distributing royalties to the parties who earned them, is the proposed use of proxy reports a fair and appropriate means of distributing remaining royalties for this period? If not, what would be a better alternative?

List of Subjects in 37 CFR Part 370

Copyright, Sound recordings.

Proposed Regulations

For the reasons set forth in the preamble, and under the authority of chapter 8, title 17, United States Code, the Copyright Royalty Judges propose to amend part 370 of Title 37 of the Code of Federal Regulations as follows:

PART 370—NOTICE AND RECORDKEEPING REQUIREMENTS FOR STATUTORY LICENSES

■ 1. The authority citation for part 370 is revised to read as follows:

Authority: 17 U.S.C. 112(e), 114(f), *803(b)*(6)(A).

■ 2. Amend § 370.3 by revising paragraph (i) to read as follows:

§ 370.3 Reports of use of sound recordings under statutory license for preexisting subscription services.

* * * * *

(i) In any case in which a preexisting subscription service has not provided a report of use required under this section for use of sound recordings under section 112(e) or section 114 of title 17 of the United States Code, or both, prior to January 1, 2019, reports of use for the corresponding calendar year filed by other preexisting subscription services may serve as the reports of use for the non-reporting service, solely for purposes of distribution of any corresponding royalties by the Collective.

■ 3. Amend § 370.4 by revising paragraph (f) to read as follows:

§ 370.4 Reports of use of sound recordings under statutory license for nonsubscription transmission services, preexisting satellite digital audio radio services, new subscription services and business establishment services.

* * * * *

(f) In any case in which a nonsubscription transmission service, preexisting satellite digital audio radio service, new subscription service, or business establishment service has not provided a report of use required under this section for use of sound recordings under section 112(e) or section 114 of title 17 of the United States Code, or both, prior to January 1, 2019, reports of use for the corresponding calendar year filed by other services of the same type may serve as the reports of use for the non-reporting service, solely for purposes of distribution of any corresponding royalties by the Collective.

Dated: May 18, 2020.

Jesse M. Feder,

Chief U.S. Copyright Royalty Judge.

[FR Doc. 2020–11131 Filed 5–28–20; 8:45 am]

BILLING CODE 1410–72–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2020–0213; FRL–10009–13–Region 9]

Air Plan Approval; California; Consumer Products Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the California Air Resources Board's Consumer Products portion of the California State Implementation Plan (SIP). These revisions concern volatile organic compound (VOC) emissions from consumer products and a supporting test method. The EPA is also proposing to approve revisions to California's Tables of Maximum Incremental Reactivity (MIR) Values to support its Aerosol Coating Products regulation. We are proposing to approve state rules to regulate these emission sources under the Clean Air Act (CAA or the Act). We are taking comments on this proposal and plan to follow with a final action.

DATES: Comments must be received on or before June 29, 2020.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2020–0213 at *https://www.regulations.gov*. For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets*.

FOR FURTHER INFORMATION CONTACT: Jeffrey Buss, EPA Region IX, 75 Hawthorne Street, San Francisco, CA 94105, (415) 947–4152, *buss.jeffrey@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to the EPA.

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I. The State's Submittal

A. What rules did the State submit?

Table 1 lists the rules addressed by this proposal with the dates that they were amended and submitted by the California Air Resources Board (CARB). The rules rely on CARB Method 310, which was submitted by CARB to the EPA on June 4, 2019.

TABLE 1—SUBMITTED RULES

Local agency	California Code of Regulations	Title	Amended [1]	Submitted
CARB	Title 17, Division 3, Chapter 1, Subchapter 8.5, Article 1.	Antiperspirants and Deodorants [2] ..	5/25/2018	06/04/2019
CARB	Title 17, Division 3, Chapter 1, Subchapter 8.5, Article 2.	Consumer Products [3]	5/25/2018	06/04/2019
CARB	Title 17, Division 3, Chapter 1, Subchapter 8.5, Article 3.	Aerosol Coating Products [4]	09/17/2014	12/01/2016
CARB	Title 17, Division 3, Chapter 1, Subchapter 8.6, Article 1.	Tables of Maximum Incremental Reactivity (MIR) Values [5].	09/17/2014	12/01/2016
CARB	Method 310—Determination of Volatile Organic Compounds (VOC) in Consumer Products and Reactive Organic Compounds (ROC) in Aerosol Coating Products.	5/25/2018	6/4/2019	

CARB's December 1, 2016 SIP revision submittal became complete by operation of law on June 1, 2017. CARB's June 4, 2019 SIP revision submittal became complete by operation of law on December 4, 2019.

B. Are there other versions of these rules?

We approved earlier versions of CARB's Consumer Products rules into the SIP as follows: Subchapter 8.5, Article 1 (''Antiperspirants and Deodorants'') at 74 FR 57074 (November 4, 2009); Article 2 (''Consumer Products'') at 79 FR 62346 (October 17, 2014); Article 3 (''Aerosol Coating Products'') at 74 FR 57074 (November 4, 2009), and Subchapter 8.6, Article 1 (''Tables of Maximum Incremental Reactivity (MIR) Values'') at 70 FR 53930 (September 13, 2005). The EPA has not previously approved CARB Method 310 as part of the California SIP.

C. What is the purpose of the submitted rule revisions?

Emissions of VOCs help produce ground-level ozone, smog and particulate matter, which harm human health and the environment. Section 110(a) of the CAA requires states to submit regulations that control VOC emissions. VOC emissions from consumer products contribute to the formation of ozone. CARB's Staff Report: Initial Statement of Reasons for Proposed Rulemaking for its consumer products amendments states, ''For more than twenty years, the Board has taken actions pertaining to the regulation of consumer products. Three regulations [Antiperspirants and Deodorants, Consumer Products, and Aerosol Coatings] have set VOC limits for 129 consumer product categories. These three regulations, when fully effective, will reduce VOC emissions by about 50 percent compared to 1990 levels.'' [6] CARB predicts that consumer products will, by 2020, become the largest source category of VOC emissions in the South Coast Air Basin,[7] which is classified as an ''Extreme'' nonattainment area for the following National Ambient Air Quality Standards (NAAQS): 1979 1-hour ozone, 1997 8-hour ozone, 2008 8-hour ozone, and the 2015 ozone NAAQS (see 40 CFR part 81).

The current amendments to Article 1 (''Antiperspirants and Deodorants'') of 17 CCR Division 3 (''Air Resources''), chapter 1 (''Air Resources Board''), subchapter 8.5 (''Consumer Products'') update certain definitions and references. The current amendments to Article 2 (''Consumer Products'') of subchapter 8.5 revise certain definitions, lower certain VOC standards, and clarify and update certain administrative and reporting requirements. Current amendments to Article 3 (''Aerosol Coating Products'') of subchapter 8.5 clarify applicability, revise certain definitions, delete mass-based VOC limits and add new, lower reactivity-based limits for general and specialty aerosol coatings. Lastly, the current amendments to Article 1 (''Tables of Maximum Incremental

[1] CARB adopted amendments to articles 1, 2 and 3 of subchapter 8.5 and article 1 of subchapter 8.6 on September 26, 2013. The California Office of Administrative Law (OAL) approved the amendments on September 17, 2014, effective January 1, 2015. CARB submitted the September 26, 2013 amendments to the EPA as a SIP revision on December 1, 2016. CARB adopted further amendments to articles 1 and 2 of subchapter 8.5 on May 25, 2018. The 2018 amendments were approved by the California OAL on December 31, 2018, effective January 1, 2019. CARB also adopted amendments to Test Method 310 on May 25, 2018. CARB submitted articles 1 and 2 and Test Method 310, as amended on May 25, 2018, to the EPA as a SIP revision by letter dated June 4, 2019.

[2] Article 1 of subchapter 8.5 includes sections 94500, 94501, 94502, 94503, 94503.5, 94504, 94505, 94506 and 94506.5.

[3] Article 2 of subchapter 8.5 includes sections 94507 through 94517.

[4] Article 3 of subchapter 8.5 includes sections 94520 through 94528.

[5] Article 1 of subchapter 8.6 includes sections 94700 and 94701.

[6] ''Staff Report: Initial Statement of Reasons for Proposed Rulemaking,'' California Air Resources Board, August 7, 2013 (''Staff Report'') at Executive Summary-2 available at *https://ww3.arb.ca.gov/regact/2013/cp2013/cp13isor.pdf*.

[7] Id. at Chapter II–9.

Reactivity (MIR) Values'') of 17 CCR Division 3, chapter 1, subchapter 8.6 (''Maximum Incremental Reactivity'') update MIR values for many individual chemical compounds and hydrocarbon solvent groupings. CARB estimates that the current amendments will result in equivalent VOC emission reductions of approximately 4 tons per day (tpd) statewide, of which approximately 1.8 tpd would occur in the area under the jurisdiction of the South Coast Air Quality Management District.

The EPA's technical support documents (TSDs) have more information about these rules.

II. The EPA's Evaluation and Proposed Action

A. How is the EPA evaluating the rules?

Rules in the SIP must be enforceable (see CAA section 110(a)(2)), must not interfere with applicable requirements concerning attainment and reasonable further progress or other CAA requirements (see CAA section 110(l)), and must not modify certain SIP control requirements in nonattainment areas without ensuring equivalent or greater emissions reductions (see CAA section 193). California's consumer products regulations cover VOC area sources. In 1998, the EPA promulgated a national rule to regulate VOC emissions from consumer products, 63 FR 48831 (September 11, 1998), and in 2008, the EPA promulgated a national rule to regulate the ozone forming potential of aerosol coating products, 73 FR 15621 (March 24, 2008). The amendments from CARB that we are proposing to approve herein contain more stringent limits for consumer products than the corresponding limits in the national consumer products VOC rule. With respect to CARB's Aerosol Coatings Products rule, we find that the amendments we are proposing to approve herein contain limits that achieve lower ozone-forming potential relative to the reactivity-based limits for aerosol coating products in the EPA's national aerosol coatings rule.

Guidance and policy documents that we used to evaluate enforceability, revision/relaxation and rule stringency requirements for the applicable criteria pollutants include the following:

1. ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations,'' EPA, May 25, 1988 (the Bluebook, revised January 11, 1990).

2. ''Guidance Document for Correcting Common VOC & Other Rule Deficiencies,'' EPA Region 9, August 21, 2001 (the Little Bluebook).

3. ''National Volatile Organic Compound Emission Standards for Consumer and Commercial Products,'' 40 CFR part 59; particularly, subpart C (''National Volatile Organic Compound Emission Standards for Consumer Products,'' and subpart E (''National Volatile Organic Compound Emission Standards for Aerosol Coatings'').

4. ''Model Rule for Consumer Products,'' Ozone Transport Commission, September 19, 2006.[8]

B. Do the rules meet the evaluation criteria?

When the EPA developed its national consumer products rules in 40 CFR part 59, we reviewed existing consumer products and aerosol coating regulations from states including those from California.[9] Since the EPA promulgated its national rules, California has periodically amended its consumer products and aerosol coating rules to add new product categories, combine similar product categories, generally reduce the VOC content limits for consumer products or product-weighted maximum incremental reactivity limits for aerosol coatings, and made other amendments to improve implementation and enforcement of its rules. CARB also updated its Tables of Maximum Incremental Reactivity consistent with newer science.

We compared CARB's amended rules against the EPA's rules and find that, overall, CARB's rules are the same or more stringent than the national rules. We noted in our TSD for aerosol coatings that there are a few limited instances where CARB adopted new aerosol coating categories or where it merged existing aerosol coating product categories, to streamline its regulation, that could result in a small emissions increase. More specifically, when CARB merged existing subcategories in the Hobby/Model/Craft aerosol coating category into a single category and merged the existing subcategories in the Shellac Sealer aerosol coating category into a single category, CARB estimated that these amendments could have resulted in approximately 0.1 tpd increase for 3–4 months, prior to 2015, if all of the products in these coatings were to reformulate.[10] CARB points out, however, that the likelihood of an increase in the ozone forming potential for these product categories is small because all products are already in full compliance with the limits that took effect January 1, 2015. This hypothetical and temporary increase in emissions (approximately 0.1 tpd increase for 3–4 months) would not occur after January 1, 2015 because the 2015 limits, with only minor exceptions, are, on the whole, more stringent than the prior (*i.e.,* 2003) limits for the affected categories whether merged or not merged.

The EPA notes that, although its national Consumer Products and Aerosol Coatings rules and CARB's rules are similar, they are not identical. Products will need to comply with the regulations in effect from each agency, and compliance with CARB's rules does not necessarily mean that the product complies with the EPA's national rules. This proposed rulemaking action is limited to an evaluation of CARB's amended rules for compliance with the requirements under the CAA and the EPA's regulations for SIP revisions and does not opine on whether a product that meets CARB's rules can also satisfy requirements in the national consumer product rules.

In sum, this action is consistent with EPA regulations, policy and guidance. The EPA has promulgated a national consumer products regulation and a national aerosol coatings regulation (40 CFR part 59, subparts C and E). There are similarities and differences between the California regulations and the national regulations. The national consumer products and aerosol coatings regulations do not preclude states from adopting more stringent regulations. In this instance, CARB's Consumer Products regulations are both broader and, in many cases, the same or more stringent than the federal regulations. As noted above, CARB estimates that the current amendments will result in equivalent VOC emission reductions of approximately 4 tons per day (tpd) statewide, of which approximately 1.8 tpd would occur in the area under the jurisdiction of the South Coast Air Quality Management District.

These rules are also consistent with CAA requirements and relevant guidance regarding enforceability and SIP revisions. The TSDs have more information on our evaluation.

C. Public Comment and Proposed Action

As authorized in section 110(k)(3) of the Act, the EPA proposes to fully approve the submitted rules because they fulfill all relevant requirements. We will accept comments from the public on this proposal until June 29, 2020. If we take final action to approve

[8] Available at *https://otcair.org/document.asp?fview=modelrules*.

[9] National Volatile Organic Compound Emission Standards for Consumer Products—proposed rule 61 FR 14531 (April 2, 1996), and National Volatile Organic Compound Emission Standards for Aerosol Coatings—proposed rule 72 FR 38951 (July 16, 2007).

[10] CARB Staff Report at Chapter IV–60 and Chapter VIII–153.

the submitted rules, our final action will incorporate these rules into the federally enforceable SIP.

III. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the CARB rules described in Table 1 of this preamble. The EPA has made, and will continue to make, these materials available through *www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely proposes to approve state regulations 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);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- 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 Clean Air Act; and
- Does not provide the EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

List of Subjects

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

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

Dated: May 18, 2020.

John Busterud,

Regional Administrator, Region IX.

[FR Doc. 2020–11260 Filed 5–28–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2019–0655; FRL–10009–73–Region 9]

Air Plan Approval; California; San Joaquin Valley Unified Air Pollution Control District and Feather River Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the San Joaquin Valley Unified Air Pollution Control District (SJVUAPCD or District) and the Feather River Air Quality Management District (FRAQMD) portions of the California State Implementation Plan (SIP) under the Clean Air Act (CAA or Act). For the SJVUAPCD, these revisions concern a rule intended to track information related to emissions of volatile organic compounds (VOCs) and particulate matter (PM) from commercial charbroilers, and an administrative rule for the registration of certain emission units historically exempted from the SJVUAPCD's permit requirements. We are proposing to approve into the California SIP amendments to a SJVUAPCD local rule, which require owners and operators of commercial underfired charbroilers to submit a one-time information report and which subject certain underfired charbroilers to registration and weekly recordkeeping requirements. We are also proposing to approve a SJVUAPCD rule addressing registration requirements for these and certain other emission units. For the FRAQMD, these revisions concern a negative declaration for the Control Techniques Guidelines (CTG) for the Oil and Natural Gas Industry. We are proposing to approve the negative declaration into the California SIP. We are taking comments on this proposal to approve the two SJVUAPCD rules and the FRAQMD negative declaration. We plan to follow with a final action.

DATES: Any comments must arrive by June 29, 2020.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2019–0655 at *https://www.regulations.gov*. For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI and multimedia submissions, and general guidance on

making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets*.

FOR FURTHER INFORMATION CONTACT: Stanley Tong, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 947–4122 or by email at *tong.stanley@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to the EPA.

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I. The State's Submittal

A. What documents did the State submit?

Table 1 lists the documents addressed by this proposal with the dates that they were adopted by the local air agencies and submitted by the California Air Resources Board (CARB).

TABLE 1—SUBMITTED DOCUMENTS

Local agency	Rule or document	Adopted/amended	Submitted
SJVUAPCD	Rule 2250—Permit-Exempt Equipment Registration	Adopted 10/19/2006	[1] 4/30/2020
SJVUAPCD	Rule 4692—Commercial Charbroiling	Amended 06/21/2018	[2] 11/21/2018
FRAQMD	Reasonably Available Control Technology (RACT) State Implementation Plan (SIP) Revision for the South Sutter County Portion of the Sacramento Metropolitan Nonattainment Area for 8-Hour ozone—Negative Declaration for Control Techniques Guidelines for the Oil and Natural Gas Industry.	Adopted 08/06/2018	[3] 12/07/2018

We find that the submittal for SJVUAPCD Rule 2250 meets the completeness criteria in 40 CFR part 51 Appendix V, which must be met before formal EPA review. On May 21, 2019, the submittal for SJVUAPCD Rule 4692 was deemed by operation of law to meet the completeness criteria in 40 CFR part 51 Appendix V. On June 7, 2019, the submittal for the FRAQMD negative declaration for the Control Techniques Guidelines for the Oil and Natural Gas Industry, EPA 453/B–16–001, (Oil and Natural Gas CTG) was deemed by operation of law to meet the aforementioned completeness criteria.

B. Are there other versions of these documents?

We approved an earlier version of SJVUAPCD Rule 4692 into the California SIP on November 3, 2011 (76 FR 68103). There is no previous version of SJVUAPCD Rule 2250 or the FRAQMD negative declaration for the Oil and Natural Gas CTG in the California SIP.

C. What is the purpose of the submitted rules and negative declaration?

Emissions of VOCs contribute to the production of ground-level ozone, smog and PM, which harm human health and the environment. Emissions of PM, including PM equal to or less than 2.5 microns in diameter ($PM_{2.5}$) and PM equal to or less than 10 microns in diameter (PM_{10}),[4] contribute to effects that are harmful to human health and the environment, including premature mortality, aggravation of respiratory and cardiovascular disease, decreased lung function, visibility impairment, and damage to vegetation and ecosystems. Section 110(a) of the CAA requires states to submit regulations that control VOC and PM emissions.

SJVUAPCD Rule 4692, Commercial Charbroiling, is designed to limit VOC and PM_{10} emissions from commercial charbroiling operations. Rule 4692 requires commercial cooking operations with chain-driven charbroilers that cook 400 pounds or more of meat per week to be equipped and operated with a catalytic oxidizer control device to minimize VOC and PM_{10} emissions. The rule requires the catalytic oxidizer to have a control efficiency of at least 83% for PM_{10} and at least 86% for VOC emissions. The June 21, 2018 amendments to Rule 4692 expand the rule to require that owners or operators of commercial cooking operations with underfired charbroilers submit a one-time report to the SJVUAPCD by January 1, 2019, and that owners of such operations with underfired charbroilers that cook quantities of meat above a specified threshold register these units pursuant to District Rule 2250 and keep weekly records of the total pounds and type of meat cooked on each such underfired charbroiler. The SJVUAPCD explains that as a first step to enable the District to implement a PM control measure for underfired charbroilers ''. . . in a cost-effective and expeditious manner . . . the District must initiate registration of affected operations . . . and a one-time information report from owners and operators of commercial cooking operations with underfired charbroilers . . .'' [5]

SJVUAPCD Rule 2250, Permit-Exempt Equipment Registration, was adopted by the District on October 19, 2006, as an alternative to its traditional permitting process. This rule is intended to apply to certain internal combustion engines, small boilers, and more recently, certain underfired charboilers, which have been traditionally exempted from the District's permit program. Rule 2250 provides the necessary administrative mechanisms to determine compliance of certain permit-exempt equipment with applicable rules and regulations. As stated above, the District's commercial charbroiler rule relies on Rule 2250 for registration requirements. Rule 4692 states that ''[t]he owner of an underfired charbroiler subject to this rule shall register such underfired charbroiler pursuant to Rule 2250 (Permit-Exempt Equipment Registration), in lieu of permitting under the requirements of Rule 2010 (Permits Required).''

CAA section 182(b)(2) requires states to submit SIP revisions to implement RACT for each category of VOC sources in the nonattainment area covered by a CTG. On October 27, 2016, (81 FR 74798), the EPA announced the

[1] This submittal was transmitted to the EPA by a letter from CARB dated April 30, 2020.

[2] This submittal was transmitted to the EPA by a letter from CARB dated November 16, 2018.

[3] This submittal was transmitted to the EPA by a letter from CARB dated December 2, 2018.

[4] PM_{10} includes particles that have aerodynamic diameters less than or equal to 10 micrometers (μm), approximately equal to one-seventh the diameter of human hair. $PM_{2.5}$ is a subset of PM_{10} particles that have aerodynamic diameters less than or equal to 2.5 μm.

[5] Letter dated June 21, 2018, from Seyed Sadredin, Executive Director, SJVUAPCD, to SJVUAPCD Governing Board, ''RE: ITEM NUMBER 9: ADOPT PROPOSED AMENDMENTS TO DISTRICT RULE 4692 (COMMERCIAL CHARBROILING).''

availability of the Oil and Natural Gas CTG. In lieu of adopting local regulations to implement the CTG, air agencies may adopt a negative declaration if the nonattainment area has no sources covered by the 2016 Oil and Natural Gas CTG.[6] The FRAQMD's negative declaration submittal is its certification that there are no sources covered by the 2016 Oil and Natural Gas CTG in the south Sutter County portion of the Sacramento Metropolitan ozone nonattainment area.[7]

The EPA's technical support documents (TSDs) for this action have more information about SJVUAPCD Rules 2250 and 4692, the FRAQMD's negative declaration, and the EPA's evaluation thereof.

II. The EPA's Evaluation and Action

A. How is the EPA evaluating the rules and negative declaration?

Generally, CAA section 110(a)(2)(A) requires SIPs to ''include enforceable emission limitations and other control measures, means, or techniques . . . as may be necessary or appropriate to meet the applicable requirements of [the CAA],'' and SIPs must be consistent with the requirements of CAA sections 110(l) and 193.

SIPs must also require RACT for each category of sources covered by a CTG document as well as each major source in ozone nonattainment areas classified as Moderate or above (see CAA sections 182(b)(2) and (f)).[8] States relying on negative declarations for CTG source categories for which the states have not adopted CTG-based regulations because they have no sources above the CTG-recommended applicability threshold must submit them for SIP approval, regardless of whether such negative declarations were made for an earlier SIP.[9] To do so, the submittal should provide reasonable assurance that no sources subject to the CTG's requirements currently exist in the relevant ozone nonattainment area.

Guidance and policy documents that we used to evaluate enforceability, revision/relaxation and rule stringency requirements for the applicable criteria pollutants include the following:

1. ''State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990,'' 57 FR 13498 (April 16, 1992); 57 FR 18070 (April 28, 1992).
2. EPA Office of Air Quality Planning and Standards, ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations,'' May 25, 1988, (the Bluebook, revised January 11, 1990).
3. EPA Region IX, ''Guidance Document for Correcting Common VOC & Other Rule Deficiencies,'' August 21, 2001 (the Little Bluebook).
4. ''State Implementation Plans for Serious PM–10 Nonattainment Areas, and Attainment Date Waivers for PM–10 Nonattainment Areas Generally; Addendum to the General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990,'' 59 FR 41998 (August 16, 1994).
5. EPA 453/B–16–001, Control Techniques Guidelines for the Oil and Natural Gas Industry.

B. Do the rules and negative declaration meet the evaluation criteria?

SJVUAPCD Rule 2250 is largely an administrative rule. We find that the rule requirements and applicability are sufficiently clear to ensure that affected sources and regulators can evaluate and determine compliance with Rule 2250 consistently. Currently, the registration requirements in Rule 2250 appear to serve simply as a means to ensure the enforceability of certain requirements imposed by other District rules for emission units historically exempted from District permit requirements, and there are no emission control requirements contained in Rule 2250. We find that Rule 2250 does not relax the SJVUAPCD's SIP-approved permit program, meets the applicable CAA requirements and guidance regarding enforceability and SIP revisions, and is approvable as a SIP-strengthening action. Our TSD for Rule 2250 has more information concerning our evaluation of the rule.

As discussed above, the 2018 amendments to SJVUAPCD Rule 4692 are largely administrative. The rule amendments require owners or operators of commercial cooking operations with underfired charbroilers to submit a one-time information report, and require owners of underfired charbroilers subject to the rule to register their units under Rule 2250 and to comply with certain weekly recordkeeping requirements. We believe Rule 4692 meets the applicable CAA requirements and guidance regarding enforceability and SIP revisions. Our TSD for Rule 4692 has more information on our evaluation of the rule.

With respect to the FRAQMD's negative declaration for the Oil and Natural Gas CTG, the FRAQMD's submittal contains the FRAQMD's certification that it has no sources in the south Sutter County portion of the Sacramento Metropolitan ozone nonattainment area subject to the Oil and Natural Gas CTG for the 2008 8-hour ozone NAAQS. The FRAQMD based its certification on a review of its permit files, a search of California's Division of Oil, Gas & Geothermal Resources (DOGGR) Well Finder website, and correspondence with current permit holders for natural gas production facilities. We accessed the DOGGR website, CARB's pollution mapping tool, and a map of the California Natural Gas Pipelines and did not find indications of operations that would be subject to the Oil and Natural Gas CTG in the south Sutter County ozone nonattainment area. Based on our review, we agree with the FRAQMD's negative declaration for the Oil and Natural Gas CTG. Our TSD for the FRAQMD negative declaration has more information on our evaluation.

C. Public Comment and Proposed Action

As authorized in section 110(k)(3) of the Act, the EPA proposes to fully approve the submitted SJVUAPCD Rules 2250 and 4692, and the FRAQMD negative declaration for the Oil and Natural Gas CTG, because they fulfill the relevant requirements in CAA sections 110(a), 110(l), 182(b)(2), and 193. We will accept comments from the public on this proposal until [Insert date 30 days after date of publication in the **Federal Register**]. If we take final action to approve the submitted documents, our final action will incorporate these documents into the federally enforceable SIP.

III. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference

[6] Memorandum dated October 20, 2016, from Anna Marie Wood, Director, Air Quality Policy Division, U.S. EPA, to Regional Air Division Directors 1–10, Subject: ''Implementing Reasonably Available Control Technology Requirements for Sources Covered by the 2016 Control Techniques Guidelines for the Oil and Natural Gas Industry,'' Question #8.

[7] The Feather River AQMD is subject CAA section 182(b)(2) RACT because its jurisdiction includes Sutter County, the southern portion of which is in an ozone nonattainment area that is classified as Severe nonattainment for the 2008 ozone NAAQS.

[8] The specific ozone RACT requirement in CAA section 182(b)(2) does not apply to Rule 4692 because there are no CTG documents for this source category and no major sources of ozone precursors subject to this rule in the SJV area. Nor does the CAA section 182(b)(2) RACT requirement apply to Rule 2250, which is largely an administrative rule, the purpose of which is to provide the District with a mechanism to determine compliance with other District regulations by certain emission units historically exempted from the District's permit requirements.

[9] 57 FR 13498, 13512 (April 16, 1992).

the SJVUAPCD rules described in Table 1 of this preamble. The EPA has made, and will continue to make, these materials available through *https://www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. 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. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, 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);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- 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 Clean Air Act; and
- Does not provide the EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

List of Subjects in 40 CFR Part 52

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

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

Dated: May 18, 2020.

John Busterud,

Regional Administrator, Region IX.

[FR Doc. 2020–11261 Filed 5–28–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2020–0223; FRL–10010–14-Region 1]

Air Plan Approval; Connecticut; Infrastructure State Implementation Plan Requirements for the 2015 Ozone Standard

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 Connecticut. This revision addresses the infrastructure requirements of the Clean Air Act (CAA or Act)—excluding the interstate transport provisions—for the 2015 ozone National Ambient Air Quality Standards (NAAQS). The infrastructure requirements are designed to ensure that the structural components of each state's air-quality management program are adequate to meet the state's responsibilities under the CAA. This action is being taken under the Clean Air Act.

DATES: Written comments must be received on or before June 29, 2020.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R01–OAR–2020–0223 at *https://www.regulations.gov,* or via email to *simcox.alison@epa.gov*. For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.* Publicly available docket materials are available at *https://www.regulations.gov* or at the U.S. Environmental Protection Agency, EPA Region 1 Regional Office, Air and Radiation Division, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays and facility closures due to COVID–19.

FOR FURTHER INFORMATION CONTACT: Alison C. Simcox, Air Quality Branch, U.S. Environmental Protection Agency, EPA Region 1, 5 Post Office Square—Suite 100, (Mail code 05–2), Boston, MA 02109—3912, tel. (617) 918–1684, email *simcox.alison@epa.gov*.

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

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I. Background and Purpose

On October 1, 2015, EPA promulgated a revision to the ozone NAAQS (2015 ozone NAAQS), lowering the level of both the primary and secondary standards to 0.070 parts per million (ppm).[1] Section 110(a)(1) of the CAA requires states to submit, within 3 years after promulgation of a new or revised standard, SIPs meeting the applicable requirements of section 110(a)(2).[2] On September 7, 2018, the Connecticut Department of Energy and Environmental Protection (CT DEEP) submitted a revision to its State Implementation Plan (SIP). The SIP revision addresses the infrastructure requirements of CAA sections 110(a)(1) and 110(a)(2)—excluding the ''Good Neighbor'' or ''transport'' provisions—for the 2015 ozone NAAQS.

A. What is the scope of this rulemaking?

EPA is acting on a SIP submission from Connecticut on the infrastructure requirements of CAA sections 110(a)(1) and 110(a)(2) for the 2015 ozone NAAQS (excluding the transport provisions).

Whenever EPA promulgates a new or revised NAAQS, CAA section 110(a)(1) requires states to make SIP submissions to provide for the implementation, maintenance, and enforcement of the NAAQS. This particular type of SIP submission is commonly referred to as an ''infrastructure SIP.'' These submissions must meet the various requirements of CAA section 110(a)(2), as applicable. Due to ambiguity in some of the language of CAA section 110(a)(2), EPA believes that it is appropriate to interpret these provisions in the specific context of acting on infrastructure SIP submissions. EPA has previously provided comprehensive guidance on the application of these provisions through a guidance document for infrastructure SIP submissions and through regional actions on infrastructure submissions.[3] Unless otherwise noted below, we are following that existing approach in acting on this submission. In addition, in the context of acting on such infrastructure submissions, EPA evaluates the submitting state's SIP for compliance with statutory and regulatory requirements, not for the state's implementation of its SIP.[4] EPA has other authority to address any issues concerning a state's implementation of the rules, regulations, consent orders, etc. that comprise its SIP.

B. What guidance is EPA using to evaluate Connecticut's infrastructure SIP submission?

EPA highlighted the statutory requirement to submit infrastructure SIPs within 3 years of promulgation of a new NAAQS in an October 2, 2007, guidance document entitled ''Guidance on SIP Elements Required Under Sections 110(a)(1) and (2) for the 1997 8-hour Ozone and $PM_{2.5}$ National Ambient Air Quality Standards'' (2007 memorandum). EPA has issued additional guidance documents and memoranda, including a September 13, 2013, guidance document entitled ''Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2)'' (2013 memorandum).

II. EPA's Evaluation of Connecticut's Infrastructure SIP for the 2015 Ozone Standard

In this notice of proposed rulemaking, EPA is proposing action on Connecticut's September 7, 2018, infrastructure SIP submission for the 2015 ozone NAAQS, excluding the interstate transport provisions (section 110(a)(2)(D)(i)), which will be addressed in a future action. In Connecticut's submission, a detailed list of Connecticut Laws and previously SIP-approved Air Quality Regulations show precisely how the various components of its EPA-approved SIP meet each of the requirements of section 110(a)(2) of the CAA for the 2015 ozone NAAQS. The following review evaluates the state's submission in light of section 110(a)(2) requirements and relevant EPA guidance. For the state's September 2018 submission, we provide an evaluation of the applicable Section 110(a)(2) elements, excluding the transport provisions.

A. Section 110(a)(2)(A)—Emission Limits and Other Control Measures

This section (also referred to in this action as an element) of the Act requires SIPs to include enforceable emission limits and other control measures, means or techniques, schedules for compliance, and other related matters. However, EPA has long interpreted emission limits and control measures for attaining the standards as being due when nonattainment planning requirements are due.[5] In the context of an infrastructure SIP, EPA is not evaluating the existing SIP provisions for this purpose. Instead, EPA is only evaluating whether the state's SIP has basic structural provisions for the implementation of the NAAQS.

In its September 2018 submittal for the 2015 ozone NAAQS, Connecticut cites provisions of Connecticut General Statutes (CGS) and Regulations of Connecticut State Agencies (RCSA) in satisfaction of element A. Connecticut Public Act No. 11–80 established the CT DEEP, and CGS section 22a–6(a)(1) provides the Commissioner of CT DEEP authority to adopt, amend or repeal environmental standards, criteria and regulations. It is under this general grant of authority that the Commissioner has adopted emissions standards and control measures for a variety of sources and pollutants.

[1] National Ambient Air Quality Standards for Ozone, Final Rule, 80 FR 65292 (October 26, 2015). Although the level of the standard is specified in the units of ppm, ozone concentrations are also described in parts per billion (ppb). For example, 0.070 ppm is equivalent to 70 ppb.

[2] SIP revisions that are intended to meet the applicable requirements of section 110(a)(1) and (2) of the CAA are often referred to as infrastructure SIPs and the applicable elements under 110(a)(2) are referred to as infrastructure requirements.

[3] EPA explains and elaborates on these ambiguities and its approach to address them in its September 13, 2013, Infrastructure SIP Guidance (available at *https://www3.epa.gov/airquality/urbanair/sipstatus/docs/Guidance_on_Infrastructure_SIP_Elements_Multipollutant_FINAL_Sept_2013.pdf*), as well as in numerous agency actions, including EPA's prior action on Connecticut's infrastructure SIP to address the 2012 $PM_{2.5}$ NAAQS. *See* 83 FR 37437 (August 1, 2018).

[4] *See Montana Envtl. Info. Ctr.* v. *Thomas,* 902 F.3d 971 (9th Cir. 2018).

[5] See, for example, EPA's final rule on ''National Ambient Air Quality Standards for Lead,'' 73 FR 66964, 67034 (November 12, 2008).

Under Element A of the September 2018 submittal, the state also cites more than 20 Regulations of Connecticut State Agencies (RCSA) that it has adopted to control the emissions related to ozone and ozone precursors (nitrogen oxides (NOx) and volatile organic compounds (VOCs). A few, with their EPA approval citation [6] are listed here: RCSA section 22a-174–3a(*l*), Nonattainment New Source Review (NNSR) (February 16, 2018, 83 FR 6968); RCSA sections 22a–174–22e, Control of nitrogen oxides emissions, –22f, High daily NO_X emitting units at non-major sources of NO_X, and -38, Municipal Waste Combustors (July 31, 2017, 82 FR 35454); and RCSA section 22a-174–30a, Stage I vapor recovery (July 31, 2017, 82 FR 35454).

EPA proposes that Connecticut meets the infrastructure requirements of section 110(a)(2)(A) for the 2015 ozone NAAQS.

B. Section 110(a)(2)(B)—Ambient Air Quality Monitoring/Data System

This section requires SIPs to provide for establishment and operation of appropriate devices, methods, systems, and procedures necessary to monitor, compile, and analyze ambient air quality data, and to make these data available to EPA upon request. Each year, states submit annual air monitoring network plans to EPA for review and approval. EPA's review of these annual monitoring plans includes our evaluation of whether the state: (i) Monitors air quality at appropriate locations throughout the state using EPA-approved Federal Reference Methods or Federal Equivalent Method monitors; (ii) submits data to EPA's Air Quality System (AQS) in a timely manner; and (iii) provides EPA Regional Offices with prior notification of any planned changes to monitoring sites or the network plan.

Connecticut statute, CGS section 22a–174(d), ''provides the Commissioner with all incidental powers necessary to control air pollution.'' CT DEEP operates an air-quality monitoring network, and EPA approved the state's 2019 Annual Air Monitoring Network Plan on August 15, 2019.[7] Furthermore, Connecticut populates EPA's Air Quality System (AQS) with air-quality monitoring data in a timely manner and provides EPA with prior notification when considering a change to its monitoring network or plan. EPA proposes that Connecticut meets the infrastructure SIP requirements of section 110(a)(2)(B) for the 2015 ozone NAAQS.

C. Section 110(a)(2)(C)—Program for Enforcement of Control Measures and for Construction or Modification of Stationary Sources

States are required to include a program providing for enforcement of all SIP measures and for the regulation of construction of new or modified stationary sources to meet new source review (NSR) requirements under prevention of significant deterioration (PSD) and nonattainment new source review (NNSR) programs. Part C of the CAA (sections 160–169B) addresses PSD, while part D of the CAA (sections 171–193) addresses NNSR requirements.

The evaluation of each state's submission addressing the infrastructure SIP requirements of section 110(a)(2)(C) covers the following: (i) Enforcement of SIP measures; (ii) PSD program for major sources and major modifications; and (iii) a permit program for minor sources and minor modifications.

Sub-Element 1: Enforcement of SIP Measures

State law provides the Commissioner of CT DEEP with the authority to enforce air pollution control requirements pursuant to CGS Title 22a. Specifically, CGS sections 22a–6 and 22a–6b authorize the Commissioner to inspect and investigate to ascertain whether violations of any statute, regulation, or permit may have occurred and to impose civil penalties. Additionally, CGS section 22a-171 requires the Commissioner to ''adopt, amend, repeal, and enforce regulations . . . and do any other act necessary to enforce the provisions of'' CGS sections 22a-170 through 22a-206, which provide CT DEEP with the authority to, among other things, enforce its regulations, issue orders to correct violations of regulations or permits, impose state administrative penalties, and seek judicial relief.

EPA proposes that Connecticut meets the enforcement of SIP measures requirements of section 110(a)(2)(C) for the 2015 ozone NAAQS.

Sub-Element 2: Psd Program for Major Sources and Major Modifications

PSD applies to new major sources or modifications made to major sources for pollutants where the area in which the source is located is in attainment of, or unclassifiable with regard to, the relevant NAAQS. EPA interprets the CAA as requiring each state to make an infrastructure SIP submission for a new or revised NAAQS demonstrating that the air agency has a complete PSD permitting program in place satisfying the current requirements for all regulated NSR pollutants. CT DEEP's EPA–approved PSD rules in RCSA sections 22a–174–1, 22a–174–2a, and 22a–174–3a contain provisions that address applicable requirements for all regulated NSR pollutants, including greenhouse gases (GHGs).

EPA's ''Final Rule to Implement the 8-Hour Ozone National Ambient Air Quality Standard—Phase 2; Final Rule to Implement Certain Aspects of the 1990 Amendments Relating to New Source Review and Prevention of Significant Deterioration as They Apply in Carbon Monoxide, Particulate Matter, and Ozone NAAQS; Final Rule for Reformulated Gasoline'' (Phase 2 Rule) was published on November 29, 2005 (70 FR 71612). Among other requirements, the Phase 2 Rule obligated states to revise their PSD programs to explicitly identify NO_X as a precursor to ozone. *See* 70 FR 71679 at 71699–700. Connecticut's EPA-approved PSD rules contain provisions needed to ensure that NO_X is treated as a precursor to ozone. EPA approved the necessary revisions to RCSA section 22a–174–3a on August 1, 2018. *See* 83 FR 37437.

Except as noted below, Connecticut has a comprehensive PSD permitting program in place covering the structural PSD permitting program requirements for all regulated NSR pollutants. EPA's PSD regulations at 40 CFR 51.166(*l*) require a State's SIP to ''provide for procedures which specify that [a]ll applications of air quality modeling . . . shall be based on the applicable models, data bases, and other requirements specified in'' EPA's Guideline on Air Quality Models in appendix W of 40 CFR part 51, which were most recently revised on January 17, 2017. 82 FR 5182; *see also* 82 FR 14324 (Mar. 20, 2017). As explained in our evaluation of section 110(a)(2)(K) requirements later in this notice, Connecticut's SIP currently provides that the DEEP Commissioner may request an owner or operator to submit an ambient air-quality impact analysis using air quality models, databases or other techniques that have been approved *by the DEEP Commissioner,* but does not specify that such models, databases, or techniques shall be based on requirements specified in appendix W. *See* RCSA § 22a–174–3a(i)(2). Connecticut DEEP has committed, however, to pursuing a revision to section 22a–174–3a(i)(2) that would provide that such models, databases, and other techniques must also have been approved by the EPA

[6] The citations reference the most recent EPA approval of the stated rule or of revisions to the rule.

[7] See EPA approval letter located in the docket for this action.

Administrator and submitting this revision, for inclusion in the SIP, to EPA within one year of our final approval of today's action. Because the EPA Administrator's approved modeling requirements are found in appendix W, this revision would satisfy the section 51.166(*l*) requirement that the SIP provide for procedures that specify that all applications of modeling be based on the requirements in appendix W. Consequently, we are proposing to conditionally approve Connecticut's submittal for the PSD sub-element of section 110(a)(2)(C) for the 2015 ozone NAAQS.

Sub-Element 3: Preconstruction Permitting for Minor Sources and Minor Modifications

To address the pre-construction regulation of the modification and construction of minor stationary sources and minor modifications of major stationary sources, an infrastructure SIP submission should identify the existing EPA-approved SIP provisions and/or include new provisions that govern the minor source pre-construction program that regulate emissions of the relevant NAAQS pollutants. On February 28, 2003, EPA approved updates to Connecticut's minor NSR program. *See* 68 FR 9009. Connecticut and EPA rely on the existing minor NSR program to ensure that new and modified sources not captured by the major NSR permitting programs do not interfere with attainment and maintenance of the 2015 ozone NAAQS.

We are proposing to find that Connecticut meets the requirement to have a SIP approved minor new source review permit program as required under section 110(a)(2)(C) for the 2015 ozone NAAQS.

D. Section 110(a)(2)(D)—Interstate Transport for the 2015 Ozone Standard

One of the structural requirements of section 110(a)(2) is section 110(a)(2)(D)(i), also known as the ''good neighbor'' provisions, which generally requires SIPs to contain adequate provisions to prohibit in-state emissions activities from having certain adverse air quality effects on neighboring states due to interstate transport of air pollution.

Section 110(a)(2)(D)(i)(I) requires SIPs to include provisions prohibiting any source or other type of emissions activity in one state from emitting any air pollutant in amounts that will contribute significantly to nonattainment, or interfere with maintenance, of the NAAQS in another state. The two provisions of this section are referred to as Prong 1 (significant contribution to nonattainment) and Prong 2 (interference with maintenance) and together make up sub-element 1 of section 110(a)(2)(D). A state's SIP submission for Prongs 1 and 2 is also referred to as a state's ''Transport SIP.'' Today's action does not include a Transport SIP (*i.e.,* Prongs 1 and 2 or sub-element 1). Connecticut's Transport SIP for the 2015 ozone NAAQS will be addressed in a future action.

Today's action, however, does contain Prong 3 and 4 of Section 110(a)(2)(D)(i)(II). These require SIPs to contain adequate provisions to prohibit emissions that will interfere with measures required to be included in the applicable implementation plan for any other state under part C to prevent significant deterioration of air quality (Prong 3) or to protect visibility (Prong 4). Today's action also includes Section 110(a)(2)(D)(ii) of the Act, which requires SIPs to contain provisions to ensure compliance with sections 115 and 126 of the Act relating to interstate and international pollution abatement.

Section 110(a)(2)(D)(i)(II)—PSD (Prong 3)

To prevent significant deterioration of air quality, this sub-element requires SIPs to include provisions that prohibit any source or other type of emissions activity in one state from interfering with measures that are required in any other state's SIP under Part C of the CAA. As explained in the 2013 memorandum, a state may meet this requirement with respect to in-state sources and pollutants that are subject to PSD permitting through a comprehensive PSD permitting program that applies to all regulated NSR pollutants and that satisfies the requirements of EPA's PSD implementation rules. As discussed above under element C, Connecticut's PSD program fully satisfies the requirements of EPA's PSD implementation rules, with one exception. As also noted in our discussion of element C, Connecticut DEEP has committed to pursuing a revision to its regulations to address the modeling issue. Consequently, EPA has in today's notice proposed to conditionally approve all of the PSD-related elements of this infrastructure SIP.

As also explained in the 2013 memorandum, a state may meet the prong 3 requirement with respect to in-state sources and pollutants subject to nonattainment NSR permitting through a fully approved NNSR program. With respect to NNSR, Connecticut regulations contain provisions for how the state must treat and control sources in nonattainment areas, consistent with 40 CFR 51.165, or Appendix S to 40 CFR 51. RCSA section 22a–174–3a(k) and 3a(i).

EPA proposes to conditionally approve Connecticut for the PSD requirements of 110(a)(2)(D)(i)(II) for the 2015 ozone NAAQS

Section 110(a)(2)(D)(i)(II)—Visibility Protection (Prong 4)

With regard to applicable requirements for visibility protection of section 110(a)(2)(D)(i)(II), states are subject to visibility and regional haze program requirements under part C of the CAA (which includes sections 169A and 169B). The 2009 memorandum, 2011 memorandum, and 2013 memorandum recommend that these requirements can be satisfied by an approved SIP addressing reasonably attributable visibility impairment, if required, or an approved SIP addressing regional haze. A fully approved regional haze SIP meeting the requirements of 40 CFR 51.308 will include all measures needed to achieve the state's apportionment of emission reduction obligations agreed upon through a regional planning process and will, therefore, ensure that emissions from sources under the air agency's jurisdiction are not interfering with measures required to be included in other air agencies' plans to protect visibility. EPA approved Connecticut's Regional Haze SIP on July 10, 2014. *See* 79 FR 39322. Accordingly, EPA proposes that Connecticut meets the visibility protection requirements of 110(a)(2)(D)(i)(II) for the 2015 ozone NAAQS.

Section 110(a)(2)(D)(ii)—Interstate Pollution Abatement.

This sub-element requires each SIP to contain provisions requiring compliance with requirements of section 126 relating to interstate pollution abatement. Section 126(a) requires new or modified sources to notify neighboring states of potential impacts from the source. The statute does not specify the method by which the source should provide the notification. States with SIP-approved PSD programs must have a provision requiring such notification by new or modified sources.

On July 24, 2015 (80 FR 43960), EPA approved revisions to Connecticut's PSD program, including the element pertaining to notification to neighboring states of the issuance of PSD permits. Therefore, we propose to approve Connecticut's compliance with the infrastructure SIP requirements of section 126(a) with respect to the 2015 ozone NAAQS. Connecticut has no

obligations under any other provision of section 126, and no source or sources within the state are the subject of an active finding under section 126 of the CAA with respect to the 2015 ozone NAAQS.

Section 110(a)(2)(D)(ii)—International Pollution Abatement

This sub-element also requires each SIP to contain provisions requiring compliance with the applicable requirements of section 115 relating to international pollution abatement. Section 115 authorizes the Administrator to require a state to revise its SIP to alleviate international transport into another country where the Administrator has made a finding with respect to emissions of the particular NAAQS pollutant and its precursors, if applicable. There are no final findings under section 115 of the CAA against Connecticut with respect to the 2015 ozone NAAQS. Therefore, EPA is proposing that Connecticut meets the applicable infrastructure SIP requirements of section 110(a)(2)(D)(ii) related to section 115 of the CAA for the 2015 ozone NAAQS.

E. Section 110(a)(2)(E)—Adequate Resources

Section 110(a)(2)(E)(i) requires each SIP to provide assurances that the state will have adequate personnel, funding, and legal authority under state law to carry out its SIP. In addition, section 110(a)(2)(E)(ii) requires each state to comply with the requirements for state boards in CAA section 128. Finally, section 110(a)(2)(E)(iii) requires that, where a state relies upon local or regional governments or agencies for the implementation of its SIP provisions, the state retain responsibility for ensuring implementation of SIP obligations with respect to relevant NAAQS. Section 110(a)(2)(E)(iii), however, does not apply to this action because Connecticut does not rely upon local or regional governments or agencies for the implementation of its SIP provisions.

Sub-Element 1: Adequate Personnel, Funding, and Legal Authority Under State Law To Carry Out Its SIP, and Related Issues

Connecticut, through its infrastructure SIP submittal, has documented that its air agency has authority and resources to carry out its SIP obligations. CGS section 22a–171 authorizes the CT DEEP Commissioner to enforce the state's air laws, accept and administer grants, and exercise incidental powers necessary to carry out the law. The Connecticut SIP, as originally submitted on March 3, 1972, and subsequently amended, provides additional descriptions of the organizations, staffing, funding and physical resources necessary to carry out the plan.

EPA proposes that Connecticut meets the infrastructure SIP requirements of this portion of section 110(a)(2)(E) for the 2015 ozone NAAQS.

Sub-Element 2: State Board Requirements Under Section 128 of the CAA

Section 110(a)(2)(E)(ii) requires each SIP to contain provisions that comply with the state board requirements of section 128 of the CAA. That provision contains two explicit requirements: (1) That any board or body which approves permits or enforcement orders under this chapter shall have at least a majority of members who represent the public interest and do not derive any significant portion of their income from persons subject to permits and enforcement orders under this chapter, and (2) that any potential conflicts of interest by members of such board or body, or the head of an executive agency with similar powers, be adequately disclosed. Section 128 further provides that a state may adopt more stringent conflicts of interest requirements and requires EPA to approve any such requirements submitted as part of a SIP.

In Connecticut, no board or body approves permits or enforcement orders; these are approved by the Commissioner of CT DEEP. Thus, with respect to this sub-element, Connecticut is subject only to the requirements of paragraph (a)(2) of section 128 of the CAA (regarding conflicts of interest).

Connecticut's September 7, 2018, infrastructure SIP refers to the state's conflict-of-interest provisions in CGS section 1–85, which apply to all state employees and public officials. Section 1–85 prevents the Commissioner from acting on a matter in which the Commissioner has an interest that is ''in substantial conflict with the proper discharge of his duties or employment in the public interest and of his responsibilities as prescribed in the laws of'' Connecticut. EPA approved CGS section 1–85 into the Connecticut SIP on June 3, 2016. *See* 81 FR 35636.

EPA proposes that Connecticut meets the infrastructure SIP requirements of this portion of section 110(a)(2)(E) for the 2015 ozone NAAQS.

F. Section 110(a)(2)(F)—Stationary Source Monitoring System

States must establish a system to monitor emissions from stationary sources and submit periodic emissions reports. Each plan shall also require the installation, maintenance, and replacement of equipment, and the implementation of other necessary steps, by owners or operators of stationary sources to monitor emissions from such sources. The state plan shall also require periodic reports on the nature and amounts of emissions and emissions-related data from such sources, and correlation of such reports by each state agency with any emission limitations or standards. Lastly, the reports shall be available at reasonable times for public inspection.

CGS section 22a–6(a)(5) authorizes the Commissioner to enter at all reasonable times, any public or private property (except a private residence) to investigate possible violations of any statute, regulation, order or permit. Additionally, CGS section 22a–174 authorizes the Commissioner to require periodic inspection of sources of air pollution and to require any person to maintain, and to submit to CT DEEP, certain records relating to air pollution or to the operation of facilities designed to abate air pollution. For monitoring possible air violations, CT DEEP implements RCSA section 22a–174–4 (Source monitoring, record keeping and reporting) to require the installation, maintenance, and use of emissions monitoring devices and to require periodic reporting to the Commissioner of the nature and extent of the emissions. On July 16, 2014, EPA approved Section 22a–174–4 into the Connecticut SIP. *See* 79 FR 41427.

Additionally, CT DEEP implements RCSA section 22a–174–5 (Methods for sampling, emissions testing, sample analysis, and reporting), which provides, among other things, specific test methods to be used to demonstrate compliance with various aspects of Connecticut's air regulations. EPA approved this rule on December 19, 1980. *See* 46 FR 43418. Furthermore, under RCSA section 22a–174–10 (Public availability of information) emissions data are to be available to the public and are not entitled to protection as a trade secret. EPA approved this rule on October 28, 1972. *See* 37 FR 23085.

Connecticut routinely collects information on air emissions from its industrial sources and makes this information available to the public. In addition, RCSA section 22a–174–10 requires that emission data made public by CT DEEP shall be presented in such a manner as to show the relationship (or correlation) between measured emissions and the applicable emission limitations or standards, as required by CAA § 110(a)(2)(F)(iii).

Therefore, EPA proposes that Connecticut meets the infrastructure SIP

requirements of section 110(a)(2)(F) for the 2015 ozone NAAQS.

G. Section 110(a)(2)(G)—Emergency Powers

This section requires that a plan provide for state authority analogous to that provided to the EPA Administrator in section 303 of the CAA, and adequate contingency plans to implement such authority. Section 303 of the CAA provides authority to the EPA Administrator to seek a court order to restrain any source from causing or contributing to emissions that present an ''imminent and substantial endangerment to public health or welfare, or the environment.'' Section 303 further authorizes the Administrator to issue ''such orders as may be necessary to protect public health or welfare or the environment'' in the event that ''it is not practicable to assure prompt protection . . . by commencement of such civil action.''

Connecticut's September 7, 2018, infrastructure SIP notes that CGS section 22a–181 (Emergency action) authorizes the Commissioner of the CT DEEP to issue an order requiring any person to immediately reduce or discontinue air pollution as required to protect the public health or safety. In addition, in a letter to EPA dated August 5, 2015, Connecticut stated that CGS section 22a–7 provides the Commissioner with emergency powers similar to those provided to the EPA Administrator in section 303.[8] Specifically, CGS section 22a–7 states that ''whenever he [the Commissioner] finds that any person is causing, engaging in or maintaining, or is about to cause, engage in or maintain, any condition or activity which, in his judgment, will result in or is likely to result in imminent and substantial damage to the environment, or to public health within the jurisdiction of the Commissioner under the provisions of chapters 440, 441, 442, 445, 446a, 446c [Air Pollution Control] . . . may, without prior hearing, issue a cease and desist order in writing to such person to discontinue, abate or alleviate such condition or activity.''

This section further provides the Commissioner with the authority to seek a court ''to enjoin any person from violating a cease and desist order issued pursuant to [section 22a–7] and to compel compliance with such order.''

Section 110(a)(2)(G) requires a state to submit for EPA approval a contingency plan to implement the air agency's emergency episode authority for any Air Quality Control Region (AQCR) within the state that is classified as Priority I, IA, or II for certain pollutants. *See* 40 CFR 51.150. This requirement may be satisfied by submitting a plan that meets the applicable requirements of 40 CFR part 51, subpart H (40 CFR 51.150 through 51.153) (''Prevention of Air Pollution Emergency Episodes'') for the relevant NAAQS. Connecticut has ''*Air pollution emergency episode procedures*'' at RCSA section 22a–174–6 that EPA has previously evaluated and approved as satisfying the requirements of section 110(a)(2)(G) in the context of ozone. *See* 81 FR 35636 (June 3, 2016); 80 FR 54471 (September 10, 2015).

We propose to find that Connecticut law provides for authority comparable to that provided to the Administrator in section 303 and adequate contingency plans to implement that authority. Therefore, EPA proposes that Connecticut meets the applicable infrastructure SIP requirements for section 110(a)(2)(G) with respect to contingency plans for the 2015 ozone NAAQS.

H. Section 110(a)(2)(H)—Future SIP Revisions

This section requires that a state's SIP provide for revision from time to time, as may be necessary, to take account of changes in the NAAQS or availability of improved methods for attaining the NAAQS and whenever EPA finds that the SIP is substantially inadequate. To address this requirement, Connecticut's September 7, 2018, infrastructure SIP submittal certifies that its SIP may be revised should EPA find that it is substantially inadequate to attain a standard or to comply with any additional requirements under the CAA, and notes that CGS section 22a–174(d) grants the Commissioner all incidental powers necessary to control and prohibit air pollution. EPA proposes that Connecticut meets the infrastructure SIP requirements of section 110(a)(2)(H) for the 2015 ozone NAAQS.

I. Section 110(a)(2)(I)—Nonattainment Area Plan or Plan Revisions Under Part D

Section 110(a)(2)(I) provides that each plan or plan revision for an area designated as a nonattainment area shall meet the applicable requirements of part D of the CAA. EPA interprets section 110(a)(2)(I) to be inapplicable to the infrastructure SIP process because specific SIP submissions for designated nonattainment areas, as required under part D, are subject to a different submission schedule under subparts 2 through 5 of part D, extending as far as 10 years following area designations for some elements, whereas infrastructure SIP submissions are due within three years after adoption or revision of a NAAQS. Accordingly, EPA takes action on part D attainment plans through separate processes.

J. Section 110(a)(2)(J)—Consultation With Government Officials; Public Notifications; Prevention of Significant Deterioration; Visibility Protection

Section 110(a)(2)(J) of the CAA requires that each SIP ''meet the applicable requirements of section 121 of this title (relating to consultation), section 127 of this title (relating to public notification), and part C of this subchapter (relating to PSD of air quality and visibility protection).'' The evaluation of the submission from Connecticut with respect to these requirements is described below.

Sub-Element 1: Consultation With Government Officials

Pursuant to CAA section 121, a state must provide a satisfactory process for consultation with local governments and Federal Land Managers (FLMs) in carrying out its NAAQS implementation requirements.

CGS section 22a–171 (Duties of Commissioner of Energy and Environmental Protection) directs the Commissioner to consult with agencies of the United States, agencies of the state, political subdivisions and industries and any other affected groups in matters relating to air quality. Additionally, CGS section 22a–171, which EPA approved into Connecticut's SIP on June 3, 2016 (81 FR 35636), directs the Commissioner to initiate and supervise statewide programs of air pollution control education and to adopt, amend, repeal and enforce air regulations.

Furthermore, RCSA section 22a–174–2a, which EPA approved into the Connecticut SIP on July 24, 2015 (80 FR 43960), directs CT DEEP to notify relevant municipal officials and FLMs, among others, of tentative determinations by CT DEEP with respect to certain permits. Therefore, EPA proposes that Connecticut meets the infrastructure SIP requirements of this portion of section 110(a)(2)(J) for the 2015 ozone NAAQS.

Sub-Element 2: Public Notification

Pursuant to CAA section 127, states must notify the public if NAAQS are exceeded in an area, advise the public of health hazards associated with exceedances, and enhance public awareness of measures that can be taken to prevent exceedances and of ways in

[8] August 5, 2015, letter from Connecticut is included in the docket for today's action.

which the public can participate in regulatory and other efforts to improve air quality.

As part of the fulfillment of CGS section 22a–171 (Duties of Commissioner of Energy and Environmental Protection), Connecticut issues press releases and posts warnings on its website advising people what they can do to help prevent NAAQS exceedances and avoid adverse health effects on poor air quality days. Connecticut is also an active partner in EPA's AirNow and Enviroflash air-quality-alert programs. In addition, in 2014, Connecticut revised CGS section 4–168 to require that state regulations be submitted through the state's e-regulations system, thus creating an additional way for the public to access any changes to state regulations.

EPA proposes that Connecticut meets the infrastructure SIP requirements of this portion of section 110(a)(2)(J) for the 2015 ozone NAAQS.

Sub-Element 3: PSD

EPA has already discussed Connecticut's PSD program in the context of infrastructure SIPs in the paragraphs addressing section 110(a)(2)(C) and 110(a)(2)(D)(i)(II) and determined that it satisfies the requirements of EPA's PSD implementation rules, with the exception of the modeling provision. Therefore, the SIP also satisfies the PSD sub-element of section 110(a)(2)(J) for the 2015 ozone NAAQS, except for the modeling requirement. For the same reasons discussed under element C above, EPA proposes to conditionally approve the SIP for the PSD sub-element of section 110(a)(2)(J) for the 2015 ozone NAAQS.

Sub-Element 4: Visibility Protection

With regard to the applicable requirements for visibility protection, states are subject to visibility and regional haze program requirements under part C of the CAA (which includes sections 169A and 169B). In the event of the establishment of a new NAAQS, however, the visibility and regional haze program requirements under part C do not change. Thus, as noted in EPA's 2013 memorandum, we find that there is no new visibility obligation ''triggered'' under section 110(a)(2)(J) when a new NAAQS becomes effective. In other words, the visibility protection requirements of section 110(a)(2)(J) are not germane to infrastructure SIPs for the 2015 ozone NAAQS.

Based on the above analysis, EPA proposes that Connecticut meets the infrastructure SIP requirements of sub-elements 1–3 of section 110(a)(2)(J) for the 2015 ozone NAAQS. We are not proposing action on sub-element 4 because, as noted above, it is not germane to infrastructure SIPs.

K. Section 110(a)(2)(K)—Air Quality Modeling/Data

Section 110(a)(2)(K) of the Act requires that a SIP provide for the performance of such air quality modeling as the EPA Administrator may prescribe for the purpose of predicting the effect on ambient air quality of any emissions of any air pollutant for which EPA has established a NAAQS, and the submission, upon request, of data related to such air quality modeling. EPA has published modeling guidelines at 40 CFR part 51, Appendix W, for predicting the effects of emissions of criteria pollutants on ambient air quality. EPA also recommends in the 2013 memorandum that, to meet section 110(a)(2)(K), a state submit or reference the statutory or regulatory provisions that provide the air agency with the authority to conduct such air quality modeling and to provide such modeling data to EPA upon request.

CGS section 22a–5 (Duties and powers of commissioner) implicitly authorizes the Commissioner of the CT DEEP to perform air quality modeling to predict effects on air quality of emissions of any NAAQS pollutant and to submit such data to EPA upon request. Connecticut reviews the potential impact of major sources consistent with 40 CFR part 51, appendix W, ''Guidelines on Air Quality Models.'' In May 2019, Connecticut DEEP issued an ''Ambient Impact Analysis Guideline'' for performing stationary source air-quality modeling in the state.[9] This guideline recommends procedures that are consistent with EPA's modeling guidelines at 40 CFR part 51, Appendix W, as revised January 2017. In its submittal, Connecticut also cites RCSA section 22a–174–3a(i), which authorizes the commissioner to request any owner or operator to submit an ambient air-quality impact analysis using applicable air quality models, databases, or other techniques approved by the commissioner. CT DEEP updated RCSA section 22a–174–3a(i), effective April 2014. In addition, CT DEEP has committed by letter dated January 27, 2020, to pursue revisions to RCSA section 22a–174–3a(i) that would further specify that the air quality models, databases, and other techniques used in an ambient air-quality impact analysis must also be approved by the EPA Administrator and to submit them to EPA within one year of EPA final approval of today's proposed action.[10] The EPA Administrator's approved air quality models, databases, and other requirements are found in EPA's modeling guidelines at 40 CFR part 51, Appendix W. Thus, with this revision, Connecticut's SIP would provide for the performance of such air quality modeling as the EPA Administrator has prescribed.

The state also collaborates with the Ozone Transport Commission (OTC) and the Mid-Atlantic Regional Air Management Association and EPA in order to perform large-scale urban airshed modeling for ozone and PM, if necessary.

Because Connecticut has committed to submit, but has not yet submitted, necessary revisions to RCSA section 22a–174–3a(i) that would provide for the performance of such air quality modeling as the EPA Administrator may prescribe, EPA proposes to conditionally approve section 110(a)(2)(K) for the 2015 ozone NAAQS.

L. Section 110(a)(2)(L)—Permitting Fees

This section requires SIPs to mandate that each major stationary source pay permitting fees to cover the cost of reviewing, approving, implementing, and enforcing a permit.

EPA's full approval of Connecticut's Title V program became effective on May 31, 2002. *See* 67 FR 31966. To gain this approval, Connecticut demonstrated the ability to collect sufficient fees to run the program. CGS section 22a–174(g) directs the Commissioner of CT DEEP to require the payment of a fee sufficient to cover the reasonable cost of reviewing and acting upon an application for, and monitoring compliance with, any state or federal permit, license, registration, order, or certificate. CT DEEP implements this directive through state regulations at RCSA sections 22a–174–26 and 22a–174–33, which contain specific requirements related to permit fees, including fees for Title V sources. EPA proposes that Connecticut meets the infrastructure SIP requirements of section 110(a)(2)(L) for the 2015 ozone NAAQS.

M. Section 110(a)(2)(M)—Consultation/ Participation by Affected Local Entities

To satisfy Element M, states must provide for consultation with, and

[9] *https://www.ct.gov/deep/lib/deep/air/compliance_monitoring/modeling/final_aiag_2018.pdf*).

[10] January 27, 2020, letter from Connecticut is included in the docket for today's action.

participation by, local political subdivisions affected by the SIP.

Connecticut's September 2018 infrastructure SIP submittal cites CGS section 22a–171, Duties of Commissioner of Energy and Environmental Protection, which authorizes the commissioner to consult with, among others, ''agencies of the state, political subdivisions and industries and any other affected groups in furtherance of the purposes of this chapter [*i.e.,* Connecticut's air pollution control laws].'' CT DEEP also references CGS section 4–168 (Notice prior to action on regulations), which provides a public participation process for all stakeholders that includes a minimum of a 30-day comment period and an opportunity for public hearing for all SIP-related actions. Connecticut notes that monthly meetings of the State Implementation Plan Revision Advisory Committee provide an additional forum for consultation and participation by the public and other stakeholders on air-quality-related topics. EPA proposes that Connecticut meets the infrastructure SIP requirements of section 110(a)(2)(M) for the 2015 ozone NAAQS.

III. Proposed Action

EPA is proposing to approve most of the elements of the infrastructure SIP submitted by Connecticut on September 7, 2018, for the 2015 ozone NAAQS. Today's action does not include the ''good neighbor'' provisions (*i.e.,* section 110(a)(2)(D)(i)), also known as a state's Transport SIP. Connecticut's Transport SIP for the 2015 ozone NAAQS will be addressed in a future action. In addition, EPA is proposing to conditionally approve the PSD-related requirements of Elements C, D, and J and to conditionally approve Element K, Air quality modeling and data, provided that the state submits in a timely manner the requirements needed for full approval of these Elements.

EPA is soliciting public comments on the issues discussed in this notice or on other relevant matters. These comments will be considered before taking final action. Interested parties may participate in the Federal rulemaking procedure by submitting written comments to this proposed rule by following the instructions listed in the **ADDRESSES** section of this **Federal Register**.

EPA's proposed action regarding each infrastructure SIP requirement for the 2015 ozone NAAQS is contained in Table 1 below.

TABLE 1—PROPOSED ACTION ON CONNECTICUT'S INFRASTRUCTURE SIP SUBMITTAL FOR THE 2015 OZONE NAAQS

Element	2015 ozone NAAQS
(A): Emission limits and other control measures	A.
(B): Ambient air quality monitoring and data system	A.
(C)1: Enforcement of SIP measures	A.
(C)2: PSD program for major sources and major modifications	CA.
(C)3: PSD program for minor sources and minor modifications	A.
(D)1: Contribute to nonattainment/interfere with maintenance of NAAQS	No action.
(D)2: PSD	CA.
(D)3: Visibility Protection	A.
(D)4: Interstate Pollution Abatement	A.
(D)5: International Pollution Abatement	A.
(E)1: Adequate resources	A.
(E)2: State boards	A.
(E)3: Necessary assurances with respect to local agencies	NA.
(F): Stationary source monitoring system	A.
(G): Emergency power	A.
(H): Future SIP revisions	A.
(I): Nonattainment area plan or plan revisions under part D	+.
(J)1: Consultation with government officials	A.
(J)2: Public notification	A.
(J)3: PSD	CA.
(J)4: Visibility protection	+.
(K): Air quality modeling and data	CA.
(L): Permitting fees	A.
(M): Consultation and participation by affected local entities	A.

In the above table, the key is as follows:

A	Approve.
CA	Conditionally Approve.
+	Not germane to infrastructure SIPs.
No action	EPA is taking no action on this infrastructure requirement.
NA	Not applicable.

EPA is proposing to conditionally approve the SIP for the PSD-related requirements of sections 110(a)(2)(C), (D)(i)(II), and (J), as well as for section 110(a)(2)(K) of the SIP revision submitted by Connecticut on September 7, 2018, as a revision to the SIP, provided that the State submits in a timely manner the necessary revisions to RCSA section 22a–174–3a(i) needed to fully approve this Element.

EPA is soliciting public comments on the issues discussed in this proposal or on other relevant matters. These comments will be considered before EPA takes final action. Interested parties may participate in the Federal rulemaking procedure by submitting comments to this proposed rule by following the instructions listed in the **ADDRESSES** section of this **Federal Register**.

Under section 110(k)(4) of the Act, EPA may conditionally approve a plan based on a commitment from the State to adopt specific enforceable measures by a date certain, but not later than 1 year from the date of approval. If EPA conditionally approves the commitment in a final rulemaking action, the State must meet its commitment to submit the necessary revisions to RCSA section 22a–174–3a(i) to satisfy requirements of section 110(a)(2)(K) of Connecticut's infrastructure SIP for the 2015 ozone NAAQS. If the State fails to do so, this action will become a disapproval one year from the date of final approval. EPA will notify the State by letter that

this action has occurred. At that time, this commitment will no longer be a part of the approved Connecticut SIP. EPA subsequently will publish a document in the **Federal Register** notifying the public that the conditional approval automatically converted to a disapproval. If the State meets its commitment, within the applicable time frame, the conditionally approved submission will remain a part of the SIP until EPA takes final action approving or disapproving the new legislative authority. If EPA disapproves the new submittal, the conditionally approved section 110(a)(2)(K) of Connecticut's infrastructure SIP for the 2015 ozone NAAQS will also be disapproved at that time. If EPA approves the submittal, section 110(a)(2)(K) of the state's infrastructure SIP for the 2015 ozone NAAQS will be fully approved in its entirety and replace the conditionally approved Element in the SIP.

If EPA determines that it cannot issue a final conditional approval or if the conditional approval is converted to a disapproval, such action will trigger EPA's authority to impose sanctions under section 110(m) of the CAA at the time EPA issues the final disapproval or on the date the State fails to meet its commitment. In the latter case, EPA will notify the State by letter that the conditional approval has been converted to a disapproval and that EPA's sanctions authority has been triggered. In addition, the final disapproval triggers the Federal implementation plan (FIP) requirement under section 110(c).

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 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 Clean Air Act. Accordingly, this proposed action merely approves 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 Orders12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not expected to be an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866;
- 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 Clean Air Act; 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, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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: May 20, 2020.

Dennis Deziel,

Regional Administrator, EPA Region 1.

[FR Doc. 2020–11335 Filed 5–28–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2020–0053; FRL–10009–84]

Receipt of a Pesticide Petition Filed for Residues of Pesticide Chemicals in or on Various Commodities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing of petition and request for comment.

SUMMARY: This document announces the Agency's receipt of an initial filing of a pesticide petition requesting the establishment or modification of regulations for residues of pesticide chemicals in or on various commodities.

DATES: Comments must be received on or before June 29, 2020.

ADDRESSES: Submit your comments, identified by docket identification (ID) number 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 Confidential Business Information (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*.

Please note that due to the public health emergency the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), main telephone number: (703) 305–7090, email address: *RDFRNotices@epa.gov*. The mailing address for each contact person is: Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. As part of the mailing address, include the contact person's name, division, and mail code. The

division to contact is listed at the end of each pesticide petition summary.

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. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html*.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. What action is the Agency taking?

EPA is announcing receipt of a pesticide petition filed under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, requesting the establishment or modification of regulations in 40 CFR part 174 and/or part 180 for residues of pesticide chemicals in or on various food commodities. The Agency is taking public comment on the request before responding to the petitioner. EPA is not proposing any particular action at this time. EPA has determined that the pesticide petition described in this document contains data or information prescribed in FFDCA section 408(d)(2), 21 U.S.C. 346a(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the pesticide petition. After considering the public comments, EPA intends to evaluate whether and what action may be warranted. Additional data may be needed before EPA can make a final determination on this pesticide petition.

Pursuant to 40 CFR 180.7(f), a summary of the petition that is the subject of this document, prepared by the petitioner, is included in a docket EPA has created for this rulemaking. The docket for this petition is available at *http://www.regulations.gov*.

As specified in FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), EPA is publishing notice of the petition so that the public has an opportunity to comment on this request for the establishment or modification of regulations for residues of pesticides in or on food commodities. Further information on the petition may be obtained through the petition summary referenced in this unit.

A. Amended Tolerance Exemptions for Inerts (Except PIPS)

PP IN–11392. (EPA–HQ–OPP–2020–0214). Technology Sciences Group Inc. (1150 18th Street NW, Suite 1000, Washington, DC 20036) on behalf of Clorox Professional Products Company, P.O. Box 493, Pleasanton, CA 94566–0803), requests to amend an exemption from the requirement of a tolerance in 40 CFR 180.940 by including an exemption under part (a) for residues of phosphoric acid (CAS Reg. no. 7664–38–2) when used as an inert ingredient in antimicrobial formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, food-processing equipment and utensils. The petitioner believes no analytical method is needed because it is not required for an exemption from the requirement of a tolerance. *Contact:* RD.

B. New Tolerance Exemptions for Inerts (Except PIPS)

PP IN–11317. (EPA–HQ–OPP–2019–0569) Ecolab Inc., 655 Lone Oak Drive, Eagan, MN 55121, requests to establish an exemption from the requirement of a tolerance for residues of adipic acid (CAS Reg. No. 124–04–9), when used as an inert ingredient (acidifier) in pesticide formulations under 40 CFR 180.940(a) at an upper limit of 100 parts per million (ppm). The petitioner believes no analytical method is needed because it is not required for an exemption from the requirement of a tolerance. *Contact:* RD.

C. New Tolerances for Non-Inerts

1. *PP 9E8786.* (EPA–HQ–OPP–2020–0232). Bayer CropScience LP, 800 N. Lindbergh Boulevard, St. Louis, MO 263167, requests to establish a tolerance in 40 CFR part 180 for residues of the fungicide, tebuconazole [alpha-[2-(4-Chlorophenyl)ethyl]-alpha-(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol] in or on rice, grain at 15.0 ppm. High performance liquid chromatography/triple stage quadrupole mass spectrometry (LC/MS/MS) was used to measure and evaluate the chemical tebuconazole. *Contact:* RD.

2. *PP 9E8811.* (EPA–HQ–OPP–2020–0009). American Spice Trade Association, 1101 17th Street NW, Suite 700, Washington, DC 20036, requests to establish a tolerance in 40 CFR part 180 for residues of the fungicide, metalaxyl: N-(2,6-dmethylphyenyl)-N-(methoxyacetyl) alanine methylester, in or on the raw agricultural commodity black pepper at 1 ppm. Gas chromatography equipped with an alkali flame ionization detector and liquid chromatography/mass spectrometric detection (LC/MS) are used to measure and evaluate the chemical metalaxyl. *Contact:* RD.

3. *PP 9E8814.* (EPA–HQ–OPP–2020–0082). Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419–8300, requests to establish a tolerance in 40 CFR part 180 for residues of the fungicide, difenoconazole, in or on olive at 2 ppm. Gas chromatography equipped with a nitrogen-phosphorous detector and liquid chromatography (LC)/mass spectrometry (MS)/(MS) are used to measure and evaluate the chemical difenoconazole. *Contact:* RD.

4. *PP 9F8801.* (EPA–HQ–OPP–2020–0225). Nippon Soda Co., Ltd., Shin-Ohtemachi Bldg. 2–1, 2-Chome Ohtemachi Chiyoda-ku, Tokyo 100–8165, Japan, requests to establish

tolerances in 40 CFR part 180 for residues of the fungicide, ipflufenoquin [2-[2-(7,8-difluoro-2-methylquinolin-3-yloxy)-6- fluorophenyl]propan-2-ol], in or on almond at 0.10 ppm; almond hulls at 3 ppm; and pome fruit (Crop Group 11–10) at 0.15 ppm; and tolerances for residues for ipflufenoquin, QP-1-14, QP-1-10, QP-1-11, and QP-1-15 (in terms of ipflufenoquin) on cattle, fat at 0.010 ppm; cattle, meat at 0.01 ppm; cattle, meat byproducts at 0.010 ppm; dairy cattle milk at 0.01 ppm; goat, fat at 0.010 ppm; goat, meat at 0.01 ppm; goat, meat byproducts at 0.010 ppm; horse, fat at 0.010 ppm; horse, meat at 0.01 ppm; horse, meat byproducts at 0.010 ppm; sheep, fat at 0.010 ppm; sheep, meat at 0.01 ppm; and sheep, meat byproducts at 0.010 ppm. High Performance Liquid Chromatography with tandem Mass Spectrometric detection (HPLC–MS/MS) is used to measure and evaluate the chemical ipflufenoquin and its metabolites. *Contact:* RD.

Authority: 21 U.S.C. 346a.

Dated: May 13, 2020.

Delores Barber,

Director, Information Technology and Resources Management Division, Office of Pesticide Programs.

[FR Doc. 2020–11636 Filed 5–28–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 228

[EPA–R09–OW–2020–0188; FRL–10009–64–Region 9]

Ocean Dumping: Modification of an Ocean Dredged Material Disposal Site Offshore of Humboldt Bay, California

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to modify the boundaries of the existing EPA-designated Humboldt Open Ocean Disposal Site (referred to hereafter as HOODS) offshore of Humboldt Bay, California, pursuant to Section 102 of the Marine Protection, Research and Sanctuaries Act, as amended (MPRSA). The primary purpose for the site modification is to enlarge the site to serve the long-term need for disposal of permitted, suitable material dredged from Humboldt Harbor and vicinity, in order to provide for continued safe navigation in the vicinity of Humboldt Bay. The modified site will be subject to monitoring and management to ensure continued protection of the marine environment.

DATES: Written comments must be received on or before June 29, 2020.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OW–2020–0188, by one of the following electronic methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments and accessing the docket and materials related to this proposed rule.
- *Email: ross.brian@epa.gov.*
- *Mail:* Note that due to the ongoing COVID–19 pandemic EPA's office building in San Francisco is closed, and physical mail may not be received for some time. Therefore, written comments should be submitted by one of the electronic methods listed above. If you are unable to access email, please contact Brian Ross via the phone number listed below and he will assist you in determining how to best to submit your comments.

Instructions: Direct your comments to Docket ID No. EPA–R09–OW–2020–0188. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through *www.regulations.gov* or email, information that you consider to be CBI or otherwise protected. The *www.regulations.gov* website is an ''anonymous access'' system, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about the EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: The Environmental Assessment (EA) supporting this proposed action, and other publicly available docket materials, are accessible electronically at *www.regulations.gov,* and also on the EPA Region 9 web page: *https://www.epa.gov/ocean-dumping/humboldt-open-ocean-disposal-site-hoods-documents.*

FOR FURTHER INFORMATION CONTACT: Brian Ross, U.S. Environmental Protection Agency Region 9, Water Division, Dredging & Sediment Management Team, 75 Hawthorne Street, San Francisco, California 94105; phone number (415) 972–3475; email: *ross.brian@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Potentially Affected Persons

Persons potentially affected by this action include those who seek or might seek permits or approval to dispose of dredged material into ocean waters pursuant to the MPRSA, 33 U.S.C. 1401 to 1445. The EPA's proposed action would be relevant to persons, including organizations and government bodies seeking to dispose of dredged material in ocean waters offshore of Humboldt Bay, California. Currently, the U.S. Army Corps of Engineers (USACE) would be most affected by this action. Potentially affected categories and persons include:

Category	Examples of potentially regulated persons
Federal Government	USACE Civil Works projects, and other Federal agencies.
Industry and general public	Port authorities, marinas and harbors, shipyards and marine repair facilities, berth owners.
State, local and tribal governments	Governments owning and/or responsible for ports, harbors, and/or berths, government agencies requiring disposal of dredged material associated with public works projects.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding persons likely to be affected by this proposed action. For any questions regarding the applicability of this proposed action to a particular entity, please refer to the contact person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

II. Background

a. History of Ocean Disposal Offshore Humboldt Bay, California

HOODS is currently the only designated ocean dredged material disposal site (ODMDS) off the coast of Humboldt Bay, California. The existing HOODS is located three to four nautical miles (nmi) offshore Humboldt Bay, and is currently 1.0 square nautical mile (nmi^2) in size. HOODS originally received final designation by the EPA in 1995. Since that time an average of one million cubic yards (cy) of dredged material has been disposed at HOODS each year. The great majority of this material has been sand dredged by USACE from the Humboldt Harbor entrance channel. The dredged sand that has been disposed at HOODS has mounded to the point where the existing site is now effectively reaching full capacity. The USACE San Francisco District and EPA Region 9 have identified a need to expand the capacity of HOODS so that ongoing dredging can continue to provide for safe navigation in and around Humboldt Bay. The need for modifying current ocean disposal capacity is based on historical dredging volumes, estimates of future dredging needs, and limited current capacity of alternatives to ocean disposal in the area.

The EPA is proposing to expand the existing HOODS boundaries rather than designate a new ocean disposal site off the coast of Humboldt Bay. Monitoring studies at HOODS have confirmed that there have been no significant adverse environmental consequences of disposal in this area, and that there are no unique or limited habitats, features, or uses of the ocean that would be affected by expanding the site. Note that proposed expansion of the existing HOODS boundary does not by itself mean that dredged material from any specific project will necessarily be approved to be disposed at the site. Before any person can ocean dump dredged material at either the existing HOODS or at the proposed expanded HOODS in the future, the EPA and the USACE must evaluate the project according to the ocean dumping regulatory criteria (40 CFR 227) and the USACE must authorize the disposal under section 103 of the MPRSA. 33 U.S.C. 1413(b). The USACE relies on the EPA's ocean dumping criteria when evaluating permit requests for (and implementing federal projects involving) the transportation of dredged material for the purpose of dumping it into ocean waters. MPRSA permits and federal projects involving ocean dumping of dredged material are subject to the EPA's review and concurrence in accordance with 33 U.S.C. 1413(c). The EPA may concur with or without conditions or decline to concur (*i.e.,* non-concur) on the permit. If the EPA concurs with conditions, the final permit or authorization must include those conditions. If the EPA declines to concur, the USACE cannot issue the permit for ocean dumping of dredged material or authorize the disposal.

The Environmental Assessment (EA) supporting this proposed action, along with other publicly available docket materials, are available for public review and are accessible electronically at *www.regulations.gov,* and also on the EPA Region 9 web page: *https://www.epa.gov/ocean-dumping/humboldt-open-ocean-disposal-site-hoods-documents*.

b. Location and Configuration of the Proposed Expanded HOODS

This action proposes the modification (by expansion) of the existing HOODS. The proposed modified HOODS is in approximately −150 to −200 feet of water (−45 to −61 meters). The proposed modified boundaries would expand the existing HOODS from a size of 1.0 nmi^2 to 4.0 nmi^2 in size. The location of the proposed modified ODMDS is bounded by the coordinates listed below. The proposed coordinates for the site are in North American Datum 83 (NAD 83):

Proposed Modified HOODS Coordinates (NAD 83)

(A) 40°50.300′ N, 124°018.017′ W
(B) 40°49.267′ N, 124°15.767′ W
(C) 40°47.550′ N, 124°17.083′ W
(D) 40°48.567′ N, 124°19.300′ W

The proposed modification of the existing HOODS boundary will allow the EPA to adaptively manage the site to maximize its capacity, manage mounding and loss of fine sediments outside of the site, and minimize the potential for any long-term adverse effects to the marine environment.

c. Management and Monitoring of the Site

The proposed modified ODMDS is expected to continue to receive suitable dredged material from the Federal navigation project at Humboldt Harbor, California, and suitable dredged material from other local and regional dredging applicants who obtain an MPRSA permit for the disposal of dredged material at the site. Under the Ocean Dumping regulations (40 CFR 228.3(b)) EPA is responsible for the management of all ocean disposal sites designated under the MPRSA. Management of the ocean disposal sites consists of regulating the times, quantity and characteristics of the material dumped at the site; establishing disposal controls, conditions and requirements to avoid and minimize potential impacts to the marine environment; and monitoring the site and surrounding environment to verify that unanticipated or significant adverse effects are not occurring from past or continued use of the ocean disposal site and that terms of the MPRSA permit are met. All persons using HOODS would be required to follow any project-specific permit conditions, as well as provisions of the Site Management and Monitoring Plan (SMMP) for the modified site as identified or incorporated into a permit or Federal project. The draft SMMP is currently available for review as an appendix to the EA, and separately at *https://www.epa.gov/ocean-dumping/humboldt-open-ocean-disposal-site-hoods-documents*. It includes management and monitoring considerations to ensure that disposal activities will not unreasonably degrade or endanger the marine environment, human health, welfare, or economic potentialities. The draft SMMP for the proposed modified ODMDS also includes management conditions to ensure adverse mounding does not occur at the site. The SMMP will be finalized by the EPA Region 9 and the USACE San Francisco District following finalization of the site modification rule and consideration of any comments received on this proposed rule and the draft SMMP.

d. MPRSA Criteria

In evaluating the proposed modified HOODS, the EPA assessed the site according to the criteria of the MPRSA, with emphasis on the general and specific regulatory criteria of 40 CFR part 228, to determine whether the proposed site designation satisfies those criteria. The EA provides a detailed evaluation of the criteria and other related factors for the modification of the existing ODMDS.

General Criteria (40 CFR 228.5)

(a) Sites must be selected to minimize interference with other activities in the

marine environment, particularly avoiding areas of existing fisheries or shellfisheries, and regions of heavy commercial or recreational navigation. (40 CFR 228.5(a)).

The original 1995 site designation identified the HOODS location as having the least potential for adverse impacts to important fish and shellfish resources (particularly including smelt, flatfish, and decapods which are all most abundant in waters shallower than 50 m in the area, closer to shore). In addition, as part of development of the EA supporting this proposed rule, the EPA completed informal consultation with the National Marine Fisheries Service (NMFS) and the U.S. Fish and Wildlife Service (USFWS), and confirmed that ongoing use of the proposed modified HOODS would continue to avoid adverse effects on existing fisheries, shellfisheries, or habitats of concern. In addition, expansion of HOODS will ensure that mounding of disposed sand does not occur to the extent that the wave climate near the Humboldt entrance channel is altered and adversely affects navigation conditions. The proposed action therefore satisfies this MPRSA criterion.

(b) Sites must be situated such that temporary perturbations to water quality or other environmental conditions during initial mixing caused by disposal operations would be reduced to normal ambient levels or undetectable contaminant concentrations or effects before reaching any beach, shoreline, marine sanctuary, or known geographically limited fishery or shellfishery. (40 CFR 228.5(b)).

The proposed HOODS modification area will be used for disposal of suitable dredged material as determined by Section 102 of the MPRSA, 33 U.S.C. 1412, and the Ocean Dumping Criteria published at 40 CFR 220–228. Based on the USACE and EPA dredged material testing and evaluation procedures, disposal of dredged maintenance material and proposed new work material is not expected to have any significant impact on water quality. The existing and proposed modified HOODS boundaries are located sufficiently far from shore and fisheries resources to allow temporary water quality disturbances caused by disposal of dredged material to be reduced to ambient conditions before reaching any environmentally sensitive areas.

(c) The sizes of disposal sites will be limited in order to localize for identification and control any immediate adverse impacts, and to permit the implementation of effective monitoring and surveillance to prevent adverse long-range impacts. Size, configuration, and location are to be determined as part of the disposal site evaluation. (40 CFR 228.5(d)).

The location, size, and configuration of the proposed modified HOODS boundaries provide long-term capacity, while also permitting effective site management, site monitoring, and limiting environmental impacts to the surrounding area to the greatest extent practicable.

The EA supporting this proposed action considered two alternatives for expanding HOODS: Expansion by 0.5 nmi to the north and west; and expansion by 1.0 nmi to the north and west (the proposed action). Under the proposed action, the effective total capacity of the site would increase from the original 25 million cy to over 100 million cy (*i.e.,* allowing for 75 million cy of additional disposal to occur), before mounding to −130 feet could again occur across the entire site. If today's disposal practices were to continue unchanged (*i.e.,* if an average of 1 million cy of entrance channel sand per year were to continue being disposed of at HOODS indefinitely), the site would reach capacity again in about 75 years. In contrast, the smaller expansion alternative would provide effective capacity for about 30 years of disposal. This smaller footprint would also limit on-site management options compared to the proposed action.

When determining the size of the proposed modified site, the ability to implement effective monitoring and surveillance programs was considered to ensure that the environment of the site could be protected, and that navigational safety would not be compromised by the mounding of dredged material. The EPA and USACE have demonstrated that the proposed modified HOODS area is feasible to manage and monitor, as shown by successful surveys in 2008 and 2014. The draft SMMP (Appendix D of the EA) describes the future monitoring and management activities that the EPA and USACE will implement to confirm that disposal at the site is not significantly affecting adjacent areas.

(d) EPA will, wherever feasible, designate ocean dumping sites beyond the edge of the continental shelf and other such sites where historical disposal has occurred. (40 CFR 228.5(e)).

The continental shelf break is approximately 10 nmi offshore at Eureka, California. The Zone of Siting Feasibility (ZSF) analysis prepared by USACE in support of the original (1995) HOODS designation determined that an economically practicable ocean disposal site serving Humboldt Harbor could not be located off the continental shelf, but rather would have to be within approximately 4 nmi from the ends of the entrance channel jetties. The existing HOODS boundary is 2.5 to 3.7 nmi from these jetties. The proposed modified HOODS boundary will extend from 3 nmi to 5 nmi from the jetties. While portions of the proposed modified site will be slightly beyond the original ZSF threshold of 4 nmi, the expansion area remains as close to the entrance channel as practicable while allowing capacity for future disposal needs without creating potentially unsafe mounding. Also, the proposed modified HOODS will occur immediately adjacent to where disposal of virtually identical dredged material has occurred for the past 25 years. This allows the least area to be disturbed overall from ongoing and future disposal activity.

Specific Criteria (40 CFR 228.6)

(1) Geographical Position, Depth of Water, Bottom Topography and Distance from Coast. (40 CFR 228.6(a)(1)).

The proposed modified HOODS is on the continental shelf three to five nmi offshore of Eureka, California, in water depths of approximately 150 to 200 feet (45 to 61 m). The seafloor in this area is comprised of a gently sloping, essentially featureless sedimentary plain that grades evenly from fine sand in shallower depths to silts in deeper areas. The EA contains a map of the proposed modified HOODS boundaries.

(2) Location in Relation to Breeding, Spawning, Nursery, Feeding, or Passage Areas of Living Resources in Adult or Juvenile Phases. (40 CFR 228.6(a)(2)).

The HOODS area provides feeding and breeding areas for common resident benthic organisms, fish, marine mammal, turtle, and seabird species. However, the proposed modified HOODS boundaries have been selected to avoid the presence of any unique or limited breeding, spawning, nursery, feeding, or passage areas for adult or juvenile phases of living resources and designation of the site is not expected to affect any geographically limited (*i.e.,* unique) resources or habitats. Informal Endangered Species Act (ESA) consultation with USFWS, and both ESA and Essential Fish Habitat (EFH) consultations with NMFS, confirmed that ongoing disposal operations in an expanded HOODS will not have significant impacts to sensitive living resources or their habitats.

(3) Location in Relation to Beaches and Other Amenity Areas. (40 CFR 228.6(a)(3)).

The proposed modified HOODS boundaries begin at approximately three nmi offshore and the square site extends two nmi further offshore. The proposed site is therefore well removed from beaches or amenity areas, and currents in the area are not expected to transport material disposed at HOODS toward shore. No significant impacts to beaches or amenity areas associated with use of the existing HOODS have been detected.

(4) Types and Quantities of Wastes Proposed to be Disposed of, and Proposed Methods of Release, including Methods of Packing the Waste, if any. (40 CFR 228.6(a)(4)).

Only suitable dredged material that meets the Ocean Dumping Criteria in 40 CFR 220–228 and receives a permit or is otherwise authorized for dumping by the USACE, and concurred with by EPA, will be disposed in the proposed modified HOODS. Dredged materials dumped in this area will be primarily sand with some fines, and most will originate from Humboldt Harbor. Average yearly disposal of dredged material is expected to continue to be approximately 1,000,000 cubic yards, primarily by government owned or contracted hopper dredges. None of the material is packaged in any manner. If a Nearshore Sand Placement Site (NSPS) is established nearby in the future, the volume of sand disposed at HOODS could substantially decrease.

(5) *Feasibility of Surveillance and Monitoring.* (40 CFR 228.6(a)(5)).

The EPA expects monitoring and surveillance at the proposed modified HOODS to continue to be feasible and readily performed from ocean or regional class research vessels. The area of the proposed modified HOODS has been successfully surveyed and sampled in 2008 and 2014. The EPA and USACE will continue to periodically monitor the site for physical, biological and chemical attributes, as described in the draft SMMP for the proposed modified site.

(6) *Dispersal, Horizontal Transport and Vertical Mixing Characteristics of the Area, including Prevailing Current Direction and Velocity, if any.* (40 CFR 228.6(a)(6)).

Ocean current monitoring in the vicinity of HOODS has confirmed both up- and down-coast current directions (depending on the season), with near-surface current velocities on the order of 25 cm/sec (0.5 knot), and deeper-water current velocities of 20 cm/sec (0.4 knot) at 45 meters deep and 15 cm/sec (0.3 knot) at the bottom. These current conditions have not adversely affected the ability to successfully and precisely dispose of dredged material permitted or authorized for disposal at HOODS in the past nor are they expected to affect disposal in the future.

(7) *Existence and Effects of Current and Previous Discharges and Dumping in the Area (including Cumulative Effects).* (40 CFR 228.6(a)(7)).

Previous disposal of dredged material at the existing HOODS has resulted in mounding of sand and burial of benthic organisms within the site but no discernable physical, chemical, or biological effects outside the site. Water quality effects from active disposal are temporary, spatially limited, and return to background levels prior to the next disposal event. Short-term, long-term, and cumulative effects of dredged material disposal in the proposed modified ODMDS would be negligible, and similar to those for the existing HOODS.

The only discharge in the vicinity of HOODS is from DG Fairhaven Power LLC's Fairhaven Power Facility on the Samoa Peninsula. Fairhaven Power is permitted to discharge a maximum of 0.35 million gallons per day of powerplant-related process water, cooling tower water, and other wastewater under terms of their current National Pollutant Discharge Elimination System (NPDES) permit No. CA0024571, issued by the State of California's North Coast Water Board. The company discharges through an existing outfall into ocean waters adjacent to the Samoa Peninsula. The NPDES permit prohibits discharging wastewater in violation of effluent standards or prohibitions established under Section 307(a) of the Clean Water Act, and it also prohibits discharging sewage sludge. The outfall is located approximately 3.5 nautical miles (6.5 kilometers) east of the HOODS. Prevailing nearshore currents would direct discharge plumes from this outfall up or down the coast, depending of the seasonal current regime, not offshore towards the HOODS. The EPA believes that there will be no adverse cumulative or synergistic impacts from the use of HOODS and discharges from the outfall described.

(8) *Interference with Shipping, Fishing, Recreation, Mineral Extraction, Desalination, Fish and Shellfish Culture, Areas of Special Scientific Importance and Other Legitimate Uses of the Ocean.* (40 CFR 228.6(a)(8)).

Minor, short-term interferences with commercial and recreational boat traffic may occur within Humboldt Harbor during dredging operations. However, interference as a result of the transport and disposal of dredged material to HOODS would be even less because disposal vessels move slowly, remain in established navigation channels, and operations are announced via U.S. Coast Guard Notice to Mariners. There may be minor, temporary interferences with recreational fishing in the area during disposal operations, but HOODS is not closed to fishing or other uses. HOODS has not been identified as an area of special scientific importance. There are no aquaculture areas near the site. The likelihood of direct interference with these activities is therefore negligible.

(9) *The Existing Water Quality and Ecology of the Sites as Determined by Available Data or Trend Assessment of Baseline Surveys.* (40 CFR 228.6(a)(9)).

Water quality at the existing HOODS is typical of waters offshore of the northern California coast. Monitoring conducted in the vicinity of the proposed modified HOODS and experience with past disposals in the existing HOODS have not identified any adverse water quality impacts from ocean disposal of dredged material. Water column plumes associated with disposal events rapidly return to background, before subsequent disposal events occur. The seafloor in this area is comprised of a gently sloping, essentially featureless sedimentary plain that grades evenly from fine sand in shallower depths to silts in deeper areas. The existing HOODS supports benthic and epibenthic fauna characteristic of the region, but there are no unique or limited habitats in the vicinity. No adverse impacts to benthos outside the disposal site have been identified based on comprehensive monitoring.

(10) *Potentiality for the Development or Recruitment of Nuisance Species in the Disposal Site.* (40 CFR 228.6(a) (10)).

Nuisance species, considered as any undesirable organism not previously existing at a location, have not been observed at, or in the vicinity of, the proposed modified HOODS. Disposal of dredged material, as well as monitoring, has been ongoing for the past 25 years. The dredged material to be disposed at the proposed modified ODMDS is expected to be from similar locations to those dredged previously and disposed of at the existing site; therefore, it expected that any benthic organisms transported to the site would be relatively similar in nature to those already present.

(11) *Existence at or in Close Proximity to the Site of any Significant Natural or Cultural Feature of Historical Importance.* (40 CFR 228.6(a) (11)).

EPA evaluated state records and coordinated with the California State Lands Commission concerning historic shipwrecks near HOODS. The EA documents that the nearest recorded shipwreck sites are close to shore and

would not be affected by ongoing disposal at HOODS. In addition, USACE conducted a survey for potential shipwrecks near the existing HOODS in 1991 (prior to designation of the existing HOODS). The USACE survey identified three magnetic anomalies that could potentially be associated with unrecorded shipwrecks. None of these anomalies has been buried by the existing HOODS disposal mound. The EPA collected high-resolution multibeam echo sounder data in 2014 at the locations of each magnetic anomaly, and confirmed that no debris, structures, or other material extended above the sediment surface at any of these locations. Because these anomalies do not extend above the surface now, and apparently have not since at least 1991, their exact character remains unknown. Ongoing disposal operations may effectively bury these features further but will not otherwise directly affect them.

III. Environmental Statutory Review

a. National Environmental Policy Act (NEPA)

The EPA's primary voluntary NEPA document for expanding the existing HOODS is the EA, prepared by the EPA in cooperation with the USACE and issued for public review simultaneously with this proposed rule. Anyone desiring to review the EA may access it at *www.regulations.gov* under Docket ID No. EPA–R09–OW–2020–0188, or at *https://www.epa.gov/ocean-dumping/humboldt-open-ocean-disposal-site-hoods-documents*. The EA and its Appendices provide the threshold environmental review for modification of HOODS. The EA discusses in detail the purpose and need for the proposed action and examines alternatives. The EPA determined that there would be no significant adverse impacts of implementing either of the action alternatives evaluated for expanding the existing HOODS.

The following three ocean disposal alternatives were considered in detail in the EA.

No Action Alternative

The No Action Alternative is defined as not modifying the size of the existing HOODS boundaries. This alternative would not address the need for an adequately sized ocean disposal site to accommodate an annual average of 1,000,000 cy of ongoing and future dredging. Because there is no other currently available disposal site for this material, rapid shoaling of the entrance channel would quickly render navigation unsafe, significantly affecting the economy of the greater Eureka area. Increased wave action in the Harbor entrance would endanger commercial ships as well as fishing and recreational vessels. This situation would discourage shippers from using Humboldt Bay for commerce, because it requires additional vessel trips to accommodate ''light-loaded'' vessels, resulting in increased transportation costs, decreased vessel safety, and maneuvering problems. This would have a long-term adverse impact on the local economy. In addition, use of the Humboldt Harbor as a port of refuge could be affected. Finally, ship groundings caused by improperly maintained deep-draft channels could result in adverse ecological repercussions (*i.e.,* oil and fuel spills). Although the No Action Alternative would not address the purpose and need for the proposed action, it was evaluated in the EA as a basis to compare the effects of the other alternatives considered.

Alternative 1: Expansion of HOODS by 1 nmi (Preferred Alternative)

Alternative 1, the Proposed Action, is to slightly reorient and expand the existing HOODS boundary by 1 nmi to the north (upcoast) and 1 nmi to the west (offshore). Alternative 1 is the Proposed Action because it would provide environmentally acceptable disposal capacity for many years, while also affording the most operational flexibility for managing the dredged material in a manner that would further minimize even physical impacts over time. This configuration would result in the total area of the site increasing from 1 square nmi to 4 square nmi. The effective total capacity of the site would increase from the original 25 million cy to over 100 million cy (*i.e.,* allowing for 75 million cy of additional disposal to occur), before mounding to −130 feet could again occur across the entire site. If current disposal practices were to continue unchanged (*i.e.,* if 1 million cy of entrance channel sand per year were to continue to be disposed of at HOODS indefinitely), the modified site would reach capacity in about 75 years.

Alternative 2: Expansion of HOODS by ½ nmi

Alternative 2 is the expansion of the existing HOODS boundary by ½ nmi to the north (upcoast) and ½ nmi to the west (offshore). This configuration would result in the total area of the site increasing from 1 square nmi to 2.25 square nmi. The effective total capacity of the site would increase from the original 25 million cy to approximately 56 million cy (*i.e.,* allowing for approximately 31 million cy of additional disposal to occur), before mounding to −130 feet could again occur across the entire site. If current disposal practices were to continue unchanged (*i.e.,* if 1 million cy per year of entrance channel sand were to continue to be disposed of at HOODS indefinitely), the modified site would reach capacity in about 31 years.

b. Magnuson-Stevens Act

The EPA submitted an EFH assessment to the NMFS, pursuant to Section 305(b), 16 U.S.C. 1855(b)(2), of the Magnuson-Stevens Fishery Conservation and Management Act, as amended, 16 U.S.C. 1801 to 1891. The EPA determined that the expansion of HOODS by one nmi (the proposed action) will not significantly affect managed species or EFH. NMFS concurred with the EPA's determination, but included one Conservation Recommendation to further minimize potential impacts. Specifically, NMFS recommended continuing to manage future disposal at HOODS by expanding the mound while leaving other areas of the site undisturbed as long as possible, rather than purposely spreading disposal events throughout the site each year. The draft SMMP (available along with this proposed rule for public comment) discusses a proposed approach for implementing this NMFS Conservation Recommendation; the SMMP will be finalized after considering any comments on it and on this proposed rule.

c. Coastal Zone Management Act

The EPA will submit a Consistency Determination (CD) package to the California Coastal Commission (CCC) following the close of the public comment period on the Environmental Assessment and the proposed rule. The CD package will specifically address how the proposed action to expand HOODS is consistent to the maximum extent practicable with the California Coastal Act Chapter 3 policies. EPA will not take final action on the proposed HOODS expansion until CCC review of EPA's consistency determination is complete and any comments have been addressed to the maximum extent practicable.

d. Endangered Species Act

The ESA, as amended, 16 U.S.C. 1531 to 1544, requires federal agencies to consult with NMFS and the USFWS to ensure that any action authorized, funded, or carried out by the federal agency is not likely to jeopardize the continued existence of any endangered

species or threatened species or result in the destruction or adverse modification of any critical habitat. The EPA completed informal ESA consultations with USFWS and NMFS, and the consultations are included as an Appendix to the EA.

Based on those consultations, the EPA determined that the proposed action will have ''no effect'' on marine mammals, sea turtles and certain seabird species. The EPA further determined that the proposed action ''may affect but is not likely to adversely affect'' anadromous fish (including the SONCC Coho ESU, the CC Chinook Salmon ESU, the NC Steelhead DPS, Eulachon, and sDPS Green Sturgeon), marbled murrelet, and short-tailed albatross. The Services concurred with these findings and no additional mitigation measures were recommended beyond the avoidance and minimization aspects of the EPA mandatory disposal site use conditions which would apply to every project using HOODS (these conditions are included with the draft SMMP, and relevant provisions of the SMMP would be identified or incorporated into subsequently issued permits and Federal projects).

e. National Historic Preservation Act

The National Historic Preservation Act (NHPA), 16 U.S.C. 470 to 470a–2, requires federal agencies to consider the effect of their actions on districts, sites, buildings, structures, or objects, included in, or eligible for inclusion in the National Register of Historic Places (NRHP). The depths of the proposed HOODS (approximately 150–200 feet) generally excludes potential habitation or resources related to human settlements in this area. Historic shipwreck remnants do exist in the general vicinity, but none would be affected by ongoing disposal activities within the expanded HOODS boundaries.

IV. Statutory and Executive Order Reviews

This rule proposes to modify the HOODS by expanding the boundaries of the existing site pursuant to Section 102 of the MPRSA, 33 U.S.C 1412. This proposed action complies with applicable executive orders and statutory provisions as follows:

a. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This proposed action is not a ''significant regulatory action'' under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).

b. Executive Order 13089: Coral Reef Protection

Executive Order 13089 on Coral Reef Protection directs agencies ''to preserve and protect the biodiversity, health, heritage, and social and economic value of U.S. coral reef ecosystems and the marine environment.'' This E.O. does not apply to this action because there are no coral reef ecosystems in the HOODS area.

c. Paperwork Reduction Act

This proposed action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Burden is defined at 5 CFR 1320.3(b). This proposed site modification does not require persons to obtain, maintain, retain, report, or publicly disclose information to or for a federal agency.

d. Regulatory Flexibility Act

The Regulatory Flexibility Act generally requires federal agencies to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impacts of this rule on small entities, small entity is defined as: (1) A small business defined by the Small Business Administration's size regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. The EPA determined that this proposed action will not have a significant economic impact on small entities because the proposed rule will only have the effect of expanding an existing site in order to allow ongoing disposal of dredged material in ocean waters. After considering the economic impacts of this proposed rule, the EPA certifies that this proposed action will not have a significant economic impact on a substantial number of small entities.

e. Unfunded Mandates Reform Act

This proposed action contains no federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1531 to 1538, for State, local, or tribal governments or the private sector. This proposed action imposes no new enforceable duty on any State, local or tribal governments or the private sector. Therefore, this proposed action is not subject to the requirements of sections 202 or 205 of the UMRA. This proposed action is also not subject to the requirements of section 203 of the UMRA because it contains no regulatory requirements that might significantly or uniquely affect small government entities. Those entities are already subject to existing permitting requirements for the disposal of dredged material in ocean waters.

f. Executive Order 13132: Federalism

This proposed action does not have federalism implications. It does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among various levels of government, as specified in Executive Order 13132. Thus, Executive Order 13132 does not apply to this proposed action. In the spirit of Executive Order 13132, and consistent with the EPA policy to promote communications between the EPA and State and local governments, the EPA specifically solicited comments on this proposed action from State and local officials.

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

This proposed action does not have tribal implications, as specified in Executive Order 13175 because the modification of the existing HOODS will not have a direct effect on 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. In addition, the depths of the proposed HOODS (approximately 150 to 200 feet) generally excludes potential habitation or resources related to human settlements. Thus, Executive Order 13175 does not apply to this action. Nevertheless, the EPA specifically solicited input from officials of 10 potentially interested tribal governments during the scoping phase of this action. The EPA is now actively soliciting comments from these tribes on this proposed action, as well as any

comments related to this Executive Order.

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. This proposed action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks. However, the EPA welcomes comments on this proposed action related to this Executive Order.

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

This proposed action is not subject to Executive Order 13211, ''Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355) because it is not a ''significant regulatory action'' as defined under Executive Order 12866. However, we welcome comments on this proposed action related to this Executive Order.

j. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, 12(d) (§ 15 U.S.C. 272), directs the EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus bodies. The NTTAA directs the EPA to provide Congress, through Office of Management and Budget, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This proposed action includes environmental monitoring and measurement as described in the EPA's proposed SMMP. The EPA will not require the use of specific, prescribed analytic methods for monitoring and managing the proposed modified HOODS. The Agency plans to allow the use of any method, whether it constitutes a voluntary consensus standard or not, that meets the monitoring and measurement criteria discussed in the SMMP. The EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially applicable voluntary consensus standards and to explain why such standards should be used in this proposed action.

k. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. The EPA determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. The EPA has assessed the overall protectiveness of modifying the existing HOODS against the criteria established pursuant to the MPRSA to ensure that any adverse impact to the environment will be mitigated to the greatest extent practicable. The EPA welcomes comments on this proposed action related to this Executive Order.

List of Subjects in 40 CFR Part 228

Environmental protection, Water pollution control.

Authority: This action is issued under the authority of Section 102 of the Marine Protection, Research, and Sanctuaries Act, as amended, 33 U.S.C. 1401, 1411, 1412.

Dated: May 14, 2020.

John W. Busterud,

Regional Administrator, EPA Region 9.

For the reasons set out in the preamble, the EPA proposes to amend chapter I, title 40 of the Code of Federal Register as follows:

PART 228—CRITERIA FOR THE MANAGEMENT OF DISPOSAL SITES FOR OCEAN DUMPING

■ 1. The authority citation for part 228 continues to read as follows:

Authority: 33 U.S.C. 1412 and 1418.

■ 2. Section 228.15 is amended by revising paragraphs (l)(10) (i) through (vi) to read as follows:

§ 228.15 Dumping sites designated on a final basis.

* * * * *

(l) * * *

(10) * * *

(i) *Location:* The coordinates of the four corners of the square site are: 40° 50.300′ North latitude (N) by 124°018.017′ West longitude (W); 40°49.267′ N by 124°15.767′ W; 40°47.550′ N by 124°17.083′ W; and 40°48.567′ N by 124°19.300′ W (North American Datum from 1983).

(ii) *Size:* 4 square nautical miles (13.4 square kilometers).

(iii) *Depth:* Water depths within the area range between approximately 150 to 200 feet (45 to 61 meters).

(iv) *Use Restricted to Disposal of:* Disposal shall be limited to dredged material determined to be suitable for ocean disposal according to 40 CFR 220–228.

(v) *Period of Use:* Continuing use over 50 years from date of site designation, subject to restrictions and provisions set forth in paragraph (l)(10)(vi) of this section.

(vi) *Restrictions/Provisions:* Site management and monitoring activities shall be implemented during the period of site use in accordance with the permit or Federal project that identifies or incorporates the most recent Site Management and Monitoring Plan (SMMP) for the HOODS published by EPA in consultation with USACE, and as may be modified in EPA concurrences for individual projects disposing at HOODS. The SMMP may be periodically revised as necessary; proposed substantive revisions to the SMMP shall be made following opportunity for public review and comment.

* * * * *

[FR Doc. 2020–11030 Filed 5–28–20; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 200513–0139]

RIN 0648–BJ12

Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Northeast Multispecies Fishery; Framework Adjustment 59

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

ACTION: Proposed rule; request for comments.

SUMMARY: This action proposes to approve and implement Framework Adjustment 59 to the Northeast Multispecies Fishery Management Plan. This rule would set or adjust catch limits for 19 of the 20 multispecies (groundfish) stocks, and make minor changes to groundfish management measures. This action is necessary to respond to updated scientific information and to achieve the goals and objectives of the fishery management plan. The proposed measures are intended to help prevent overfishing, rebuild overfished stocks, achieve optimum yield, and ensure that management measures are based on the best scientific information available.

DATES: Comments must be received by June 15, 2020.

ADDRESSES: You may submit comments, identified by NOAA–NMFS–2020–0013 by either of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal eRulemaking Portal.

1. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2020-0013;*

2. Click the ''Comment Now!'' icon and complete the required fields; and

3. Enter or attach your comments.

- *Mail:* Submit written comments to Michael Pentony, Regional Administrator, National Marine Fisheries Service, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope, ''Comments on the Proposed Rule for Groundfish Framework Adjustment 59.''

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by us. 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 information submitted voluntarily by the sender will be publicly accessible. We will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Copies of Framework Adjustment 59, including the draft Environmental Assessment, the Regulatory Impact Review, and the Regulatory Flexibility Act Analysis prepared by the New England Fishery Management Council in support of this action, are available from Thomas A. Nies, Executive Director, New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950. The supporting documents are also accessible via the internet at: *http://www.nefmc.org/management-plans/northeast-multispecies* or *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Liz Sullivan, Fishery Policy Analyst, phone: 978–282–8493; email: *Liz.Sullivan@noaa.gov*.

SUPPLEMENTARY INFORMATION:

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2. Fishing Year 2020 Shared U.S./Canada Quotas
3. Catch Limits for Fishing Years 2020–2022
4. Regulatory Corrections Under Secretarial Authority

1. Summary of Proposed Measures

This action would implement the management measures in Framework Adjustment 59 to the Northeast Multispecies Fishery Management Plan (FMP). The New England Fishery Management Council reviewed the proposed regulations and deemed them consistent with, and necessary to implement, Framework 59 in a March 20, 2020, letter from Council Chairman Dr. John Quinn to Regional Administrator Michael Pentony. Under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), we are required to publish proposed rules for comment after preliminarily determining whether they are consistent with applicable law. The Magnuson-Stevens Act allows us to approve, partially approve, or disapprove measures that the Council proposes based only on whether the measures are consistent with the fishery management plan, plan amendment, the Magnuson-Stevens Act and its National Standards, and other applicable law. Otherwise, we must defer to the Council's policy choices. We are seeking comments on the Council's proposed measures in Framework 59. Through Framework 59, the Council proposes to:

- Set fishing year 2020 shared U.S./Canada quotas for Georges Bank (GB) yellowtail flounder and eastern GB cod and haddock;
- Set 2020–2022 specifications, including catch limits, for 15 groundfish stocks;
- Adjust 2020 allocations for four groundfish stocks: Gulf of Maine (GOM) winter flounder, Southern New England/Mid-Atlantic (SNE/MA) winter flounder, redfish, and ocean pout;
- Address commercial/recreational allocation issues raised by new Marine Recreational Information Program (MRIP) data; and
- Revise the GB cod Incidental Catch total allowable catch (TAC) to remove the allocation to the Closed Area I Hook Gear Haddock Special Access Program (SAP).

This action also proposes regulatory corrections that are not part of Framework 59, but that may be considered and implemented under our section 305(d) authority in the Magnuson-Stevens Act to make changes necessary to carry out the FMP. We are proposing these corrections in conjunction with the Framework 59 proposed measures for expediency purposes. These proposed corrections are described in Section 4, Regulatory Corrections under Secretarial Authority.

2. Fishing Year 2020 Shared U.S./Canada Quotas

Management of Transboundary Georges Bank Stocks

Eastern GB cod, eastern GB haddock, and GB yellowtail flounder are jointly managed with Canada under the United States/Canada Resource Sharing Understanding. The Transboundary Management Guidance Committee (TMGC) is a government-industry committee made up of representatives from the United States and Canada. For historical information about the TMGC see: *http://www.bio.gc.ca/info/intercol/tmgc-cogst/index-en.php*. Each year, the TMGC recommends a shared quota for each stock based on the most recent stock information and the TMGC's harvest strategy. The TMGC's harvest strategy for setting catch levels is to maintain a low to neutral risk (less than 50 percent) of exceeding the fishing mortality limit for each stock. The harvest strategy also specifies that when stock conditions are poor, fishing mortality should be further reduced to

promote stock rebuilding. The shared quotas are allocated between the United States and Canada based on a formula that considers historical catch (10-percent weighting) and the current resource distribution (90-percent weighting).

For GB yellowtail flounder, the Council's Scientific and Statistical Committee (SSC) also recommends an acceptable biological catch (ABC) for the stock. The ABC is typically used to inform the U.S. TMGC's discussions with Canada for the annual shared quota. Although the stock is jointly managed with Canada, and the TMGC recommends annual shared quotas, the Council may not set catch limits that would exceed the SSC's recommendation. The SSC does not recommend ABCs for eastern GB cod and haddock because they are management units of the total GB cod and haddock stocks. The SSC recommends overall ABCs for the total GB cod and haddock stocks. The shared U.S./Canada quota for eastern GB cod and haddock is included in these overall ABCs, and must be consistent with the SSC's recommendation for the total GB stocks.

2020 U.S./Canada Quotas

The Transboundary Resources Assessment Committee conducted assessments for the three transboundary stocks in July 2019, and detailed summaries of these assessments can be found at: *https://www.nefsc.noaa.gov/assessments/trac/*. The TMGC met in September 2019 to recommend shared quotas for 2020 based on the updated assessments, and the Council adopted the TMGC's recommendations in Framework 59. The proposed 2020 shared U.S./Canada quotas, and each country's allocation, are listed in Table 1.

TABLE 1—PROPOSED 2020 FISHING YEAR U.S./CANADA QUOTAS AND PERCENT OF QUOTA ALLOCATED TO EACH COUNTRY

[Mt, live weight]

Quota	Eastern GB cod	Eastern GB haddock	GB yellowtail flounder
Total Shared Quota	650	30,000	162
U.S. Quota	188.5 (29%)	16,200 (54%)	120 (74%)
Canadian Quota	461.5 (71%)	13,800 (46%)	42 (26%)

The proposed 2020 U.S. quota for eastern GB cod would represent a 0.3-percent decrease compared to 2019; the proposed 2020 U.S. quota for eastern GB haddock and GB yellowtail flounder would represent 8-percent and 13-percent increases, respectively, compared to 2019. The slight quota decrease for eastern GB cod is due to a decision on how to round the share of the quota allotted to each country. The increase for eastern GB haddock is due to an increase in the portion of the shared quota that is allocated to the United States. The increase for GB yellowtail flounder is due to an increase in the total shared ABC for the stock, despite a slight decrease in the portion of the quota that is allocated to the United States. For a more detailed discussion of the TMGC's 2020 catch advice, see the TMGC's guidance document that will be posted at: *https://www.greateratlantic.fisheries.noaa.gov/*. The 2020 U.S. quotas for eastern GB cod, eastern GB haddock, and GB yellowtail that are proposed in Framework Adjustment 59, if approved, will replace the 2020 quotas previously specified for these stocks (85 FR 23229; April 27, 2020). This is discussed further in Section 3, Catch Limits for the 2020–2022 Fishing Years.

The regulations implementing the U.S./Canada Resource Sharing Understanding require deducting any overages of the U.S. quota for eastern GB cod, eastern GB haddock, or GB yellowtail flounder from the U.S. quota in the following fishing year. If catch information for the 2019 fishing year indicates that the U.S. fishery exceeded its quota for any of the shared stocks, we will reduce the respective U.S. quotas for the 2020 fishing year in a future management action, as close to May 1, 2020, as possible. If any fishery that is allocated a portion of the U.S. quota exceeds its allocation and causes an overage of the overall U.S. quota, the overage reduction would be applied only to that fishery's allocation in the following fishing year. This ensures that catch by one component of the overall fishery does not negatively affect another component of the overall fishery.

3. Catch Limits for Fishing Years 2020–2022

Summary of the Proposed Catch Limits

Tables 2 through 11 show the proposed catch limits for the 2020–2022 fishing years. A brief summary of how these catch limits were developed is provided below. More details on the proposed catch limits for each groundfish stock can be found in Appendix II (Calculation of Northeast Multispecies Annual Catch Limits, FY 2020–FY 2022) to the Framework 59 Environmental Assessment (see **ADDRESSES** for information on how to get this document).

Through Framework 59, the Council proposes to adopt catch limits for 14 groundfish stocks for the 2020–2022 fishing years based on stock assessments completed in 2019, and fishing year 2020–2021 specifications for GB yellowtail flounder. Framework 57 (83 FR 18985; May 1, 2018) previously set 2020 quotas for the five groundfish stocks not assessed in 2019 (GOM winter flounder, SNE/MA winter flounder, redfish, ocean pout, and Atlantic wolffish), based on assessments conducted in 2017. This action would include minor adjustments for four of these stocks (excluding Atlantic wolffish) for fishing year 2020. Table 2 details the percent change in the 2020 catch limit compared to the 2019 fishing year.

Because Framework 59 is not in place in time for the May 1 start to the fishing year, the fishing year 2020 quotas previously set by Frameworks 57 and 58 are in effect from May 1, 2020, through April 20, 2021, unless and until replaced by the quotas proposed in this action. However, neither framework set a 2020 quota for the eastern portion of the GB cod and haddock stocks. A default quota for eastern GB cod and eastern GB haddock required by current regulations will be in effect from May 1, 2020, through July 31, 2020, unless and until replaced by the quotas proposed in this action (85 FR 23229; April 27, 2020).

Overfishing Limits and Acceptable Biological Catches

The overfishing limit (OFL) is calculated to set the maximum amount of fish that can be caught in a year,

without constituting overfishing. The ABC is typically set lower than the OFL to account for scientific uncertainty. For GB cod, GB haddock, and GB yellowtail flounder, the total ABC is reduced by the amount of the Canadian quota (see Table 1 for the Canadian and U.S. shares of these stocks). Although the TMGC recommendations were only for fishing year 2020, the portion of the shared quota allocated to Canada in fishing 2020 was used to project U.S. ABCs for GB yellowtail for 2021 and for GB cod and haddock for 2021 and 2022. This avoids artificially inflating the U.S. ABC up to the total ABC for the 2021 and 2022 fishing years. The TMGC will make new recommendations for 2021, which would replace any quotas for these stocks set in this action.

Additionally, although GB winter flounder, white hake, and Atlantic halibut are not jointly managed with Canada, there is some Canadian catch of these stocks. Because the total ABC must account for all sources of fishing mortality, expected Canadian catch of GB winter flounder (26 mt), white hake (39 mt), and Atlantic halibut (41 mt) is deducted from the total ABC. The U.S. ABC is the amount available to the U.S. fishery after accounting for Canadian catch (see Table 2). For stocks without Canadian catch, the U.S. ABC is equal to the total ABC.

Based on the SSC's recommendation, the Council proposed continuing to set the OFLs as unknown for GB yellowtail flounder, witch flounder, and Atlantic halibut. Additionally, the SSC recommended setting the OFL for GB cod as unknown. Empirical stock assessments are used for these four stocks, and these assessments can no longer provide quantitative estimates of the status determination criteria nor were appropriate proxies for stock status determination developed. In the temporary absence of an OFL, given recent catch data and estimated trends in stock biomass showing stability or improvement in stock conditions, we have preliminarily determined that these ABCs are a sufficient limit for preventing overfishing and are consistent with the National Standards. This action does not propose any changes to the status determination criteria for these stocks.

TABLE 2—PROPOSED FISHING YEARS 2020–2022 OVERFISHING LIMITS AND ACCEPTABLE BIOLOGICAL CATCHES

[Mt, live weight]

Stock	2020		Percent change from 2019	2021		2022	
	OFL	U.S. ABC		OFL	U.S. ABC	OFL	U.S. ABC
GB Cod	UNK	1,291	−29	UNK	1,291	UNK	1,291
GOM Cod	724	552	−21	929	552	1,150	552
GB Haddock	184,822	131,567	126	116,883	76,537	114,925	75,056
GOM Haddock	25,334	19,696	58	21,521	16,794	14,834	11,526
GB Yellowtail Flounder	UNK	120	13	UNK	120	.....	.....
SNE/MA Yellowtail Flounder	31	22	−68	71	22	184	22
CC/GOM Yellowtail Flounder	1,136	823	61	1,076	823	1,116	823
American Plaice	4,084	3,155	96	3,740	2,881	3,687	2,825
Witch Flounder	UNK	1,483	49	UNK	1,483	UNK	1,483
GB Winter Flounder	790	561	−31	944	561	1,590	561
GOM Winter Flounder*	596	447	0	.....	.....	.....	.....
SNE/MA Winter Flounder*	1,228	727	0	.....	.....	.....	.....
Redfish*	15,852	11,942	1	.....	.....	.....	.....
White Hake	2,857	2,147	−27	2,906	2,147	2,986	2,147
Pollock	35,358	27,447	−32	28,475	22,062	21,744	16,812
N. Windowpane Flounder	84	59	−36	84	59	84	59
S. Windowpane Flounder	568	426	−10	568	426	568	426
Ocean Pout*	169	127	0	.....	.....	.....	.....
Atlantic Halibut	UNK	106	2	UNK	106	0	106
Atlantic Wolffish*	120	90	0				

CC = Cape Cod; N = Northern; S = Southern; UNK = Unknown.

*The GOM winter flounder, SNE/MA winter flounder, redfish, ocean pout, and Atlantic wolffish stocks have U.S. ABCs previously approved in Framework 57, based on the 2017 assessments. All other stocks' proposed ABCs based on the 2019 assessments.

Note: An empty cell indicates no OFL/ABC is adopted for that year. These catch limits would be set in a future action.

Annual Catch Limits

Development of Annual Catch Limits

The U.S. ABC for each stock is divided among the various fishery components to account for all sources of fishing mortality. An estimate of catch expected from state waters and the other sub-component (*e.g.,* non-groundfish fisheries or some recreational groundfish fisheries) is deducted from the U.S. ABC. The remaining portion of the U.S. ABC is distributed to the fishery components that receive an allocation for the stock. Components of the fishery that receive an allocation have a sub-annual catch limit (sub-ACL) set by reducing their portion of the ABC to account for management uncertainty and are subject to AMs if they exceed their respective catch limit during the fishing year. For GOM cod and haddock only, the U.S. ABC is first divided between the commercial and recreational fisheries, before being further divided into sub-component and sub-ACLs. This process is described fully in Appendix II of the Framework 59 Environmental Assessment.

Sector and Common Pool Allocations

For stocks allocated to sectors, the commercial groundfish sub-ACL is further divided into the non-sector (common pool) sub-ACL and the sector sub-ACL, based on the total vessel enrollment in sectors and the cumulative potential sector contributions (PSC) associated with those sectors. The sector and common pool sub-ACLs proposed in this action are based on final fishing year 2020 sector rosters. All permits enrolled in a sector, and the vessels associated with those permits, had until April 30, 2020, to withdraw from a sector and fish in the common pool for the 2020 fishing year. In addition to the enrollment delay, all permits that changed ownership after the roster deadline were

able to join a sector (or change sector) through April 30, 2020.

Common Pool Total Allowable Catches

The common pool sub-ACL for each allocated stock (except for SNE/MA winter flounder) is further divided into trimester TACs. Table 5 summarizes the common pool trimester TACs proposed in this action.

Incidental catch TACs are also specified for certain stocks of concern (*i.e.,* stocks that are overfished or subject to overfishing) for common pool vessels fishing in the special management programs (*i.e.,* special access programs (SAP) and the Regular B Days-at-Sea (DAS) Program), in order to limit the catch of these stocks under each program. Tables 7 through 10 summarize the proposed Incidental Catch TACs for each stock and the distribution of these TACs to each special management program.

Recreational Allocations

Amendment 16 established the method for determining the commercial and recreational allocations of GOM cod and haddock based on the ratio of reported landings (for commercial and recreational) and discards (commercial only) for the time period 2001–2006 using data from the Groundfish Assessment Review Meeting III (GARM III). Based on this method and the catch data available at the time, since 2010 the recreational fishery has been annually allocated 33.7 percent of the GOM cod ABC and 27.5 percent of the GOM haddock ABC. As described above, the recreational sub-ACL is set by reducing the recreational portion of the ABC to account for management uncertainty.

The 2019 stock assessments used updated data to assess groundfish stocks including GOM cod and haddock. Data changes since 2010 include updated commercial landings and discards, the incorporation of recreational discards, and Marine Recreational Information Program (MRIP) recreational landings and discards, which were revised following the transition from the telephone-based effort survey to the mail-based effort survey and the re-calibration of recreational catch estimates from 1981 to the present. Framework 59 proposes to apply the same method approved in Amendment 16 but with the revised data for the same time period of 2001–2006, which would result in a revised recreational allocation of 37.5 percent for GOM cod and 33.9 percent for GOM haddock. The remaining portion of the ABC (62.5 percent for GOM cod, 66.1 percent for GOM haddock) would be allocated to the commercial fisheries, which include the federal commercial groundfish fishery, state commercial fishery, and other federal fisheries. Table 11 shows the original and proposed split in allocations as a percentage for the commercial and recreational fisheries for GOM cod and haddock.

Closed Area I Hook Gear Haddock SAP

The Omnibus Essential Fish Habitat Amendment (OHA2) (83 FR 15240; April 9, 2018) eliminated the year-round closure of Closed Area I. When OHA2 eliminated Closed Area I, the Closed Area I Hook Gear Haddock SAP was no longer necessary, because the geographic area is now an open area accessible to groundfish vessels using hook gear (with the exception of the Seasonal Closed Area I North closure). In a separate rulemaking, we have proposed to remove the Closed Area I Hook Gear Haddock SAP under the Regional Administrator's authority (85 FR 19129; April 6, 2020). Because changes in allocations require Council action, the Council proposed in Framework 59 to remove the portion of the Incidental Catch Total Allowable Catch (TAC) for GB cod that is allocated to the Closed Area I Hook Gear Haddock SAP. The allocation of the GB cod Incidental Catch TAC would remain for the Regular B Days-at-Sea Program and the Eastern U.S./Canada Haddock SAP (Table 8).

Default Catch Limits for Future Fishing Years

Framework 53 established a mechanism for setting default catch limits in the event a future management action is delayed. If final catch limits have not been implemented by the start of a fishing year on May 1, then default catch limits are set at 35 percent of the previous year's catch limit. The default catch limits are effective until July 31 of that fishing year, or when replaced by new catch limits, whichever happens first. If the default value is higher than the Council's recommended catch limit for the upcoming fishing year, the default catch limits will be equal to the Council's recommended catch limits for the applicable stocks for the upcoming fishing year. Because groundfish vessels are not able to fish if final catch limits have not been implemented, this measure was established to minimize disruption to the groundfish fishery. Additional description of the default catch limit mechanism is provided in the preamble to the Framework 53 final rule (80 FR 25110; May 1, 2015).

TABLE 3—PROPOSED CATCH LIMITS FOR THE 2020 FISHING YEAR

[Mt, live weight]

Stock	Total ACL	Groundfish sub-ACL	Sector sub-ACL	Common pool sub-ACL	Recreational sub-ACL	Midwater trawl fishery	Scallop fishery	Small-mesh fisheries	State waters sub-component	Other sub-component
	A to H	A + B + C	A	B	C	D	E	F	G	H
GB Cod	1,234	1,073	1,041	31					19	142
GOM Cod	523	468	267	9	193				48	7
GB Haddock	124,969	121,864	119,410	2,454		2,447			0	658
GOM Haddock	18,580	18,267	11,754	303	6,210	183			65	65
GB Yellowtail Flounder	116	95	92	3			18.6	2.2	0.0	0.0
SNE/MA Yellowtail Flounder	21	15	12	3			2		0	4
CC/GOM Yellowtail Flounder	787	688	656	32					58	41
American Plaice	3,000	2,937	2,859	78					32	32
Witch Flounder	1,414	1,310	1,275	35					44	59
GB Winter Flounder	545	522	502	21					0	22
GOM Winter Flounder	432	287	272	14					139	7
SNE/MA Winter Flounder	699	539	475	63					36	124
Redfish	11,351	11,231	11,085	147					60	60

TABLE 3—PROPOSED CATCH LIMITS FOR THE 2020 FISHING YEAR—Continued

[Mt, live weight]

Stock	Total ACL	Groundfish sub-ACL	Sector sub-ACL	Common pool sub-ACL	Recreational sub-ACL	Midwater trawl fishery	Scallop fishery	Small-mesh fisheries	State waters sub-component	Other sub-component
	A to H	A + B + C	A	B	C	D	E	F	G	H
White Hake	2,041	2,019	1,995	24					11	11
Pollock	26,184	23,989	23,752	236					1,098	1,098
N. Windowpane Flounder	55	38	na	38			12		1	5
S. Windowpane Flounder	412	48	na	48			143		26	196
Ocean Pout	120	92	na	92					1	27
Atlantic Halibut	102	77	na	77					21	4
Atlantic Wolffish	84	82	na	82					1	1

na: Not allocated to sectors.

TABLE 4—PROPOSED CATCH LIMITS FOR THE 2021 FISHING YEAR

[Mt, live weight]

Stock	Total ACL	Groundfish sub-ACL	Sector sub-ACL	Common pool sub-ACL	Recreational sub-ACL	Midwater trawl fishery	Scallop fishery	Small-mesh fisheries	State waters sub-component	Other sub-component
	A to H	A + B + C	A	B	C	D	E	F	G	H
GB Cod	1,234	1,073	1,041	31					19	142
GOM Cod	523	468	267	9	193				48	7
GB Haddock	72,699	70,892	69,465	1,428		1,424			0	383
GOM Haddock	15,843	15,575	10,022	258	5,295	156			56	56
GB Yellowtail Flounder	116	95	92	3			19	2	0	0
SNE/MA Yellowtail Flounder	21	15	12	3			2		0	4
CC/GOM Yellowtail Flounder	787	688	656	32					58	41
American Plaice	2,740	2,682	2,611	71					29	29
Witch Flounder	1,414	1,310	1,275	35					44	59
GB Winter Flounder	545	522	502	21					0	22
GOM Winter Flounder*			0	0						
SNE/MA Winter Flounder*			0	0						
Redfish*			0	0						
White Hake	2,041	2,019	1,995	24					11	11
Pollock	21,047	19,282	19,092	190					882	882
N. Windowpane Flounder	55	38	na	38			12		1	5
S. Windowpane Flounder	412	48	na	48			143		26	196
Ocean Pout*										
Atlantic Halibut	102	77	na	77					21	4
Atlantic Wolffish*										

na: Not allocated to sectors.

*These stocks only have an allocation for fishing year 2020, previously approved in Framework 57.

TABLE 5—PROPOSED CATCH LIMITS FOR THE 2022 FISHING YEAR

[Mt, live weight]

Stock	Total ACL	Groundfish sub-ACL	Sector sub-ACL	Common pool sub-ACL	Recreational sub-ACL	Midwater trawl fishery	Scallop fishery	Small-mesh fisheries	State waters sub-component	Other sub-component
	A to H	A + B + C	A	B	C	D	E	F	G	H
GB Cod	1,234	1,073	1,041	31					19	142
GOM Cod	523	468	267	9	193				48	7
GB Haddock	71,292	69,521	68,120	1,400		1,396			0	375
GOM Haddock	10,873	10,690	6,879	177	3,634	107			38	38
GB Yellowtail Flounder**			0	0						
SNE/MA Yellowtail Flounder	21	15	13	3			2		0	4
CC/GOM Yellowtail Flounder	787	688	656	32					58	41
American Plaice	2,687	2,630	2,560	70					28	28
Witch Flounder	1,414	1,310	1,275	35					44	59
GB Winter Flounder	545	522	502	21					0	22

TABLE 5—PROPOSED CATCH LIMITS FOR THE 2022 FISHING YEAR—Continued

[Mt, live weight]

Stock	Total ACL	Groundfish sub-ACL	Sector sub-ACL	Common pool sub-ACL	Recreational sub-ACL	Midwater trawl fishery	Scallop fishery	Small-mesh fisheries	State waters sub-component	Other sub-component
	A to H	A + B + C	A	B	C	D	E	F	G	H
GOM Winter Flounder*			0	0						
SNE/MA Winter Flounder*			0	0						
Redfish*			0	0						
White Hake	2,041	2,019	1,995	24					11	11
Pollock	16,039	14,694	14,549	145					672	672
N. Windowpane Flounder	55	38	na	38			12		1	5
S. Windowpane Flounder	412	48	na	48			143		26	196
Ocean Pout*										
Atlantic Halibut	102	77	na	77					21	4
Atlantic Wolffish*										

na: Not allocated to sectors.

*These stocks only have an allocation for fishing year 2020, previously approved in Framework 57.

** Framework 59 proposes allocations for GB yellowtail flounder for fishing years 2020 and 2021 only.

TABLE 6—PROPOSED FISHING YEARS 2020–2022 COMMON POOL TRIMESTER TACS

[Mt, live weight]

Stock	2020			2021			2022		
	Trimester 1	Trimester 2	Trimester 3	Trimester 1	Trimester 2	Trimester 3	Trimester 1	Trimester 2	Trimester 3
GB Cod	8.8	10.7	11.9	8.8	10.7	11.9	8.8	10.7	11.9
GOM Cod	4.3	2.9	1.6	4.3	2.9	1.6	4.3	2.9	1.6
GB Haddock	662.7	810.0	981.8	385.5	471.2	571.1	378.1	462.1	560.1
GOM Haddock	81.8	78.8	142.4	69.8	67.2	121.5	47.9	46.1	83.4
GB Yellowtail Flounder	0.6	1.0	1.7	0.6	1.0	1.7			
SNE/MA Yellowtail Flounder	0.6	0.8	1.5	0.6	0.8	1.5	0.6	0.8	1.5
CC/GOM Yellowtail Flounder	18.0	8.2	5.4	18.0	8.2	5.4	18.0	8.2	5.4
American Plaice	57.6	6.2	14.0	52.6	5.7	12.8	51.6	5.6	12.6
Witch Flounder	19.5	7.1	8.9	19.5	7.1	8.9	19.5	7.1	8.9
GB Winter Flounder	1.7	5.0	14.2	1.7	5.0	14.2	1.7	5.0	14.2
GOM Winter Flounder	5.4	5.5	3.6						
Redfish	36.7	45.5	64.6						
White Hake	9.3	7.6	7.6	9.3	7.6	7.6	9.3	7.6	7.6
Pollock	66.2	82.7	87.5	53.2	66.5	70.3	40.5	50.7	53.6

TABLE 7—PROPOSED COMMON POOL INCIDENTAL CATCH TACS FOR THE 2020–2022 FISHING YEARS

[Mt, live weight]

Stock	Percentage of common pool sub-ACL	2020	2021	2022
GB Cod	1.68	0.53	0.53	0.53
GOM Cod	1	0.09	0.09	0.09
GB Yellowtail Flounder	2	0.07	0.07	
CC/GOM Yellowtail Flounder	1	0.32	0.32	0.32
American Plaice	5	3.89	3.56	3.49
Witch Flounder	5	1.77	1.77	1.77
SNE/MA Winter Flounder	1	0.63		

TABLE 8—PERCENTAGE OF INCIDENTAL CATCH TACS DISTRIBUTED TO EACH SPECIAL MANAGEMENT PROGRAM

Stock	Regular B DAS program (%)	Closed Area I hook gear haddock SAP (%)	Eastern U.S./CA haddock SAP (%)
GB Cod	60	0	40
GOM Cod	100	n/a	n/a
GB Yellowtail Flounder	50	n/a	50
CC/GOM Yellowtail Flounder	100	n/a	n/a
American Plaice	100	n/a	n/a
Witch Flounder	100	n/a	n/a

TABLE 8—PERCENTAGE OF INCIDENTAL CATCH TACS DISTRIBUTED TO EACH SPECIAL MANAGEMENT PROGRAM—Continued

Stock	Regular B DAS program (%)	Closed Area I hook gear haddock SAP (%)	Eastern U.S./CA haddock SAP (%)
SNE/MA Winter Flounder	100	n/a	n/a

TABLE 9—PROPOSED FISHING YEARS 2020–2022 INCIDENTAL CATCH TACS FOR EACH SPECIAL MANAGEMENT PROGRAM

[Mt, live weight]

Stock	Regular B DAS program			Closed Area I hook gear haddock SAP	Eastern U.S./Canada haddock SAP		
	2020	2021	2022	2020–2022	2020	2021	2022
GB Cod	0.32	0.32	0.32	0.0	0.21	0.21	0.21
GOM Cod	0.09	0.09	0.09	n/a	n/a	n/a	n/a
GB Yellowtail Flounder	0.03	0.03	.....	n/a	0.03	0.03	.....
CC/GOM Yellowtail Flounder	0.32	0.32	0.32	n/a	n/a	n/a	n/a
American Plaice	3.89	3.56	3.49	n/a	n/a	n/a	n/a
Witch Flounder	1.77	1.77	1.77	n/a	n/a	n/a	n/a
SNE/MA Winter Flounder	0.63	.....	.....	n/a	n/a	n/a	n/a

TABLE 10—PROPOSED FISHING YEARS 2020–2022 REGULAR B DAS PROGRAM QUARTERLY INCIDENTAL CATCH TACS

[Mt, live weight]

Stock	2020				2021				2022			
	1st quarter (13%)	2nd quarter (29%)	3rd quarter (29%)	4th quarter (29%)	1st quarter (13%)	2nd quarter (29%)	3rd quarter (29%)	4th quarter (29%)	1st quarter (13%)	2nd quarter (29%)	3rd quarter (29%)	4th quarter (29%)
GB Cod	0.04	0.09	0.09	0.09	0.04	0.09	0.09	0.09	0.04	0.09	0.09	0.09
GOM Cod	0.01	0.03	0.03	0.03	0.01	0.03	0.03	0.03	0.01	0.03	0.03	0.03
GB Yellowtail Flounder	0.004	0.010	0.010	0.010	0.00	0.01	0.01	0.01	.....	.....	.....	.....
CC/GOM Yellowtail Flounder	0.04	0.09	0.09	0.09	0.04	0.09	0.09	0.09	0.04	0.09	0.09	0.09
American Plaice	0.51	1.13	1.13	1.13	0.46	1.03	1.03	1.03	0.45	1.01	1.01	1.01
Witch Flounder	0.23	0.51	0.51	0.51	0.23	0.51	0.51	0.51	0.23	0.51	0.51	0.51
SNE/MA Winter Flounder	0.08	0.18	0.18	0.18	.....	.....	.....	.....	.....	.....	.....	.....

TABLE 11—CURRENT AND PROPOSED ALLOCATIONS, BY PERCENTAGE, FOR COMMERCIAL AND RECREATIONAL GULF OF MAINE COD AND HADDOCK FISHERIES

	GOM cod		GOM haddock	
	Commercial	Recreational	Commercial	Recreational
Current (%)	66.3	33.7	72.5	27.5
Proposed (%)	62.5	37.5	66.1	33.9

4. Regulatory Corrections Under Secretarial Authority

The following corrections are being made using Magnuson-Stevens Act section 305(d) authority to ensure that FMPs or amendments are implemented in accordance with the Magnuson-Stevens Act.

Authority To Change Gear Standard

In 2007, the Council recommended that the Regional Administrator implement gear performance standards that gear must meet before being considered for use in the Regular B DAS Program and the Eastern U.S./Canada Haddock SAP. On December 26, 2007, we published a final rule approving the Council's recommended gear standards (72 FR 72965). In updating the regulations to reflect the new gear standards, the 2007 rule inadvertently removed the portion of the regulations that gave the Regional Administrator authority to approve additional gear standards, if recommended by the Council. This rulemaking proposes to revise the regulatory text to correctly reflect the Council's original intent.

Citation for Windowpane Flounder Accountability Measure

The regulations regarding the windowpane flounder accountability measures include a process by which the AM may be reduced. The regulations implementing this provision include an incorrect citation to a paragraph that was moved to a new location. This action proposes to correct this citation.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has made a preliminary determination that this proposed rule is consistent with Framework 59, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment. In making the final determination, we will consider the data, views, and comments received during the public comment period.

This proposed rule has been determined to be not significant for purposes of Executive Order (E.O.) 12866.

This proposed rule does not contain policies with federalism or takings implications as those terms are defined in E.O. 13132 and E.O. 12630, respectively.

An Initial Regulatory Flexibility Analysis (IRFA) was prepared for this proposed rule, as required by section 603 of the Regulatory Flexibility Act, 5 U.S.C. 603. The IRFA describes the economic impact that this proposed rule would have on small entities, including small businesses, and also determines ways to minimize these impacts. The IRFA includes this section of the preamble to this rule and analyses contained in Framework 59 and its accompanying EA/RIR/IRFA. A copy of the full analysis is available from the Council (see **ADDRESSES**). A summary of the IRFA follows.

Description of the Reasons Why Action by the Agency Is Being Considered and Statement of the Objectives of, and Legal Basis for, This Proposed Rule

This action proposes management measures, including annual catch limits, for the multispecies fishery in order to prevent overfishing, rebuild overfished groundfish stocks, and achieve optimum yield in the fishery. A complete description of the action, why it is being considered, and the legal basis for this action are contained in Framework 59, and elsewhere in the preamble to this proposed rule, and are not repeated here.

Description and Estimate of the Number of Small Entities to Which This Proposed Rule Would Apply

The proposed rule would impact the recreational groundfish, Atlantic sea scallop, small mesh multispecies, Atlantic herring, and large-mesh non-groundfish fisheries. Individually-permitted vessels may hold permits for several fisheries, harvesting species of fish that are regulated by several different FMPs, even beyond those impacted by the proposed action. Furthermore, multiple-permitted vessels and/or permits may be owned by entities affiliated by stock ownership, common management, identity of interest, contractual relationships, or economic dependency. For the purposes of the Regulatory Flexibility Act analysis, the ownership entities, not the individual vessels, are considered to be the regulated entities.

As of June 1, 2019, NMFS had issued 801 commercial limited-access groundfish permits associated with vessels (including those in confirmation of permit history), 589 party/charter groundfish permits, 730 limited access and general category Atlantic sea scallop permits, 716 small mesh multispecies permits, 78 Atlantic herring permits, and 834 large-mesh non-groundfish permits (limited access summer flounder and scup permits). Therefore, 3,748 permits are potentially regulated by this action. When accounting for overlap between fisheries, this number falls to 2,177 permitted vessels. Each vessel may be individually owned or part of a larger corporate ownership structure, and for RFA purposes it is the ownership entity that is ultimately regulated by the proposed action. Ownership entities are identified on June 1st of each year based on the list of all permit numbers, for the most recent complete calendar year, that have applied for any type of Northeast Federal fishing permit. The current ownership data set is based on calendar year 2018 permits and contains gross sales associated with those permits for calendar years 2016 through 2018.

For RFA purposes only, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (NAICS code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $11 million for all its affiliated operations worldwide. The determination as to whether the entity is large or small is based on the average annual revenue for the three years from 2016 through 2018. The Small Business Administration (SBA) has established size standards for all other major industry sectors in the U.S., including for-hire fishing (NAICS code 487210). These entities are classified as small businesses if combined annual receipts are not in excess of $8.0 million for all its affiliated operations. As with commercial fishing businesses, the annual average of the three most recent years (2016–2018) is utilized in determining annual receipts for businesses primarily engaged in for-hire fishing.

Ownership data collected from permit holders indicate that there are 1,670 distinct business entities that hold at least one permit regulated by the proposed action. All 1,670 business entities identified could be directly regulated by this proposed action. Of these 1,670 entities, 1,010 are commercial fishing entities, 305 are for-hire entities, and 355 did not have revenues (were inactive in 2018). Of the 1,010 commercial fishing entities, 998 are categorized as small entities and 12 are categorized as large entities per the NMFS guidelines. All 305 for-hire entities are categorized as small businesses.

Description of the Projected Reporting, Record-Keeping, and Other Compliance Requirements of This Proposed Rule

The proposed action does not contain any new collection-of-information requirements under the Paperwork Reduction Act (PRA).

Federal Rules Which May Duplicate, Overlap, or Conflict With This Proposed Rule

The proposed action does not duplicate, overlap, or conflict with any other Federal rules.

Description of Significant Alternatives to the Proposed Action Which Accomplish the Stated Objectives of Applicable Statutes and Which Minimize Any Significant Economic Impact on Small Entities

The economic impacts of each proposed measure is discussed in more detail in sections 6.5 and 7.12 of the Framework 59 Environmental Assessment and are not repeated here. For the updated groundfish specifications, the No Action alternative was the only other alternative considered by the Council. The proposed action is predicted to generate $70.1 million in gross revenues on the sector portion of the commercial groundfish trips, $4.8 million more than No Action. Fishery-wide operating profits are predicted to be $3.7 million more than No Action. Therefore, there are no alternatives that would have lower economic impacts.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Reporting and recordingkeeping requirements.

Dated: May 13, 2020.

Samuel D. Rauch, III,

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

For the reasons stated in the preamble, 50 CFR part 648 is proposed to be amended as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

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

■ 2. Section 648.85 is amended by:
■ a. Revising paragraph (b)(5)(ii), and
■ b. Adding (b)(6)(iv)(J)(*2*)(*iii*).

The revision and addition read as follows:

§ 648.85 Special management programs.

* * * * *

(b) * * *

(5) * * *

(ii) *GB cod.* The Incidental Catch TAC for GB cod specified in this paragraph (b)(5) shall be subdivided as follows: 60 percent to the Regular B DAS Program described in paragraph (b)(6) of this section and 40 percent to the Eastern U.S./Canada Haddock SAP described in paragraph (b)(8) of this section.

(6) * * *

(iv) * * *

(J) * * *

(*2*) * * *

(*iii*) The Council may recommend to the Regional Administrator an addition or modification to the gear standards specified in paragraph (b)(6)(iv)(J)(*2*)(*i*) or (*ii*) of this section, and the Regional Administrator may approve the Council's recommendation in a manner consistent with the Administrative Procedure Act. If the Regional Administrator does not approve an addition or modification to the gear standards as recommended by the Council, NMFS must provide a written rationale to the Council regarding its decision not to do so.

* * * * *

■ 3. In § 648.90, revise paragraph (a)(5)(i)(E)(*5*) to read as follows:

§ 648.90 NE multispecies assessment, framework procedures and specifications, and flexible area action system.

* * * * *

(a) * * *

(5) * * *

(i) * * *

(E) * * *

(*5*) *Reducing the size of an AM.* If the overall northern or southern windowpane flounder ACL is exceeded by more than 20 percent and NMFS determines that the stock is rebuilt, and the biomass criterion, as defined by the Council, is greater than the most recent fishing year's catch, then only the small AM may be implemented as described in paragraph (a)(5)(i)(E) of this section, consistent with the Administrative Procedure Act. This provision applies to a limited access NE multispecies permitted vessel fishing on a NE multispecies DAS or sector trip, and to all vessels fishing with trawl gear with a codend mesh size equal to or greater than 5 inches (12.7 cm) in other, non-specified sub-components of the fishery, including, but not limited to, exempted fisheries that occur in Federal waters and fisheries harvesting exempted species specified in § 648.80(b)(3).

* * * * *

[FR Doc. 2020–10732 Filed 5–26–20; 4:15 pm]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 85, No. 104
Friday, May 29, 2020

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

Forest Service

Information Collection: Special Use Administration

AGENCY: Forest Service, USDA.

ACTION: Notice; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Forest Service is seeking comments from all interested individuals and organizations on the extension with revision of a currently approved information collection, Special Use Administration.

DATES: Comments must be received in writing on or before July 28, 2020 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Comments concerning this notice should be addressed to Volunteers & Service Program Manager, USDA Forest Service, Attention: Lands, USDA Forest Service—Washington Office, 1400 Independence Avenue Southwest, Mailstop 1124, Washington, DC 20250–1124. Comments also may be submitted via facsimile to 703–605–5117 or by email to: *reply_lands_staff@usda.gov*.

The public may inspect comments received at the USDA Forest Service—Washington Office during normal business hours. Visitors are encouraged to call ahead to facilitate entry to the building.

FOR FURTHER INFORMATION CONTACT: Mark Chandler, Realty Specialist, at 202–205–1117 or via email at *mark.chandler@usda.gov*.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 between 8 a.m. and 8 p.m. Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Title: Special Use Administration.

OMB Number: 0596–0082.

Expiration Date of Approval: January 31, 2017.

Type of Request: Extension with revision.

Abstract: The information collection requirements are necessary for the Forest Service to issue and administer special use authorizations that allow the public to use and occupy National Forest System (NFS) lands under these authorities. The information collected is used by Forest Service officials (unless otherwise noted) to ensure that uses of NFS lands are authorized, in the public interest, and compatible with the Agency's mission; and/or record authorization of use granted by appropriate Forest Service officials.

In addition, the Department of the Interior (DOI) statutes for the Bureau of Land Management (BLM), Fish and Wildlife Service (FWS), National Park Service (NPS), and Bureau of Reclamation (BOR) along with the statute for the U.S. Army Corp of Engineers (USACE) authorize its collection of information and will utilize form SF–299 ''Application for Transportation and Utility Systems and Facilities on Federal Lands.''

Several statutes authorize the Forest Service to issue and administer authorizations for use and occupancy of NFS lands and collect information from the public for those purposes. The laws authorizing the collection of this information include the Organic Administration Act of 1897 (16 U.S.C. 551); Title V of the Federal Land Policy and Management Act of 1976 (FLPMA, 43 U.S.C. 1761–1771); Act of March 4, 1915 (16 U.S.C. 497); Alaska Term Permit Act of March 30, 1948 (48 U.S.C. 341); Act of September 3, 1954 (68 Stat. 1146; 43 U.S.C. 931c, 931d); National Forest Ski Area Permit Act (16 U.S.C. 497b); section 28 of the Mineral Leasing Act (30 U.S.C. 185); National Forest Roads and Trails Act (FRTA, 16 U.S.C. 532–538); section 7 of the Granger-Thye Act (16 U.S.C. 480d); Act of May 26, 2000 (16 U.S.C. 460l–6d); Federal Lands Recreation Enhancement Act (16 U.S.C. 6801–6814); Archeological Resource Protection Act of October 31, 1979 (16 U.S.C. 1996); and the Rural Electrification Act of 1936, as amended.

Forest Service regulations implementing these authorities, found at 36 CFR part 251, subpart B, contain information collection requirements, including submission of applications, execution of forms, and imposition of terms and conditions that entail information collection requirements, such as the requirement to submit annual financial information, to prepare and update an operating plan; to prepare and update a maintenance plan, and to submit compliance reports and information updates.

The information helps the Forest Service identify the environmental and social impacts of special uses for purposes of compliance with the National Environmental Policy Act and program administration. In addition, the Forest Service uses the information to ascertain whether the land use fee(s) charged for special use authorizations are based on market value.

Information collection occurs via application forms, as well as terms and conditions in special use authorizations and operating plans. There are six categories of information collected:

(1) Information required from proponents and applicants to evaluate proposals and applications to use or occupy NFS lands,

(2) Information required from applicants to complete special use authorizations,

(3) Annual financial information required from holders to determine land use fees,

(4) Information required from holders to prepare and update operating plans,

(5) Information required from holders to prepare and update maintenance plans, and

(6) Information required from holders to complete compliance reports and informational updates.

The six categories cover all information collection requirements involved in administration of the Special Uses program, including application and reporting forms; authorization forms; supplemental special use authorization clauses in Forest Service Handbook 2709.11, chapter 50; and information collection requirements not associated with an approved standard form.

These six categories demonstrate the complexity of the special uses program and the importance of standard forms in administration of the program. Special use authorizations encompass a variety of activities ranging from individual private uses to large-scale commercial

facilities and public services. Examples of authorized special uses include public and private road rights-of-way, apiaries, domestic water supply conveyance systems, telephone and electric service rights-of-way, oil and gas pipeline rights-of-way, communications facilities, hydroelectric power-generating facilities, ski areas, resorts, marinas, municipal sewage treatment plants, and public parks and playgrounds.

Category 1: The Application Process

1. IRS form W–9, *Request for Taxpayer Identification Number and Certification,* is used to certify permit holder federal tax classification as part of the permit authorization and administration process.

2. FS–2300–43, *Special Use Application and Permit for Government-Owned Buildings,* is the form used by the Forest Service to collect information and to issue permits for use of government-owned facilities on NFS lands.

3. FS–2700–3a, *Holder-Initiated Revocation of Existing Authorization and Request for a Special Use Permit,* is used to facilitate issuance of a new authorization when there is a change in ownership of authorized improvements or a change in control of the holder of a special use authorization.

4. FS–2700–3b, *Special Use Application and Permit for Noncommercial Group Use,* provides information used to evaluate requests to use NFS lands for noncommercial gatherings involving 75 or more people, such as a wedding or an activity involving the exercise of First Amendment rights, and to authorize such requests.

5. FS–2700–3c, *Special Use Application and Permit for Recreation Events,* is used to collect information needed to evaluate requests to use NFS lands for events involving an entry or participation fee, such as an endurance ride, and to authorize such requests.

6. FS–2700–3f, *Special Use Application and Permit, Temporary Permit for Outfitting and Guiding,* is the form used by the Forest Service to collect information and to issue temporary permits to use NFS lands for Outfitting and Guiding services.

7. FS–2700–10, *Technical Data for Communications Uses,* is the form used by the Forest Service to collect information and to evaluate the compatibility of communications equipment at a communications site to minimize frequency interference and other compatibility problems.

8. FS–2700–11, *Agreement Concerning a Small Business Administration Loan for a Holder of a Special Use Permit,* is the form used by the Forest Service to collect information and to enter into agreement with a holder, a lender, and the U.S. Small Business Administration (SBA) regarding a loan guaranteed by the SBA.

9. FS–2700–12, *Agreement Concerning a Loan for a Holder of a Special Use Permit,* is the form used by the Forest Service to collect information and to enter into an agreement with a holder and a lender regarding a loan not guaranteed by the SBA.

10. FS–2700–30, *Application for Permit for Archaeological Investigations,* is the form used by the Forest Service to collect information and to evaluate the financial capability and qualifications of an applicant to undertake archaeological investigations on NFS lands.

11. FS–2700–33, *Additional Insured Endorsement for a Special Use Authorization,* is the form used by the Forest Service to collect information and to name the United States as an additional insured in an insurance policy issued to the holder of a special use authorization.

12. FS–2700–34, *Prospectus for Campground and Related Granger-Thye Concessions,* is used to select the most qualified applicant to operate a concession campground in a competitive process.

13. FS–2800–22A, *Application for Authorization for Paleontological Resources Research or Collection, ((re-numbered from and separated from FS–2700–36)),* is the form used by the Forest Service to collect information required to evaluate an applicant's proposal for paleontological research or collection to ensure compliance with statutory and regulatory requirements established for such activities.

14. FS–2800–22B, *Authorization to Conduct Paleontological Resources Research or Collection, ((re-numbered from and separated from FS–2700–36)),* is the form used by the Forest Service to establish stipulations for the performance of authorized activities related to paleontological research or collection.

15. FS–2800–22C, *Paleontological Investigation Report Form, ((re-numbered from and separated from FS–2700–36)),* is the form used by the Forest Service to collect information necessary to evaluate a permit holder's compliance with requirements established under an authorization to conduct paleontological research or collection, and to collect information used in the monitoring of paleontological resources.

16. FS–2800–22D, *Paleontological Specimen Data Form, ((re-numbered from and separated from FS–2700–36)),* is the form used by the Forest Service to provide information regarding specimens collected under authorization, which remain Federal property, and which must be deposited in an approved repository institution.

17. FS–6500–24, *Financial Statement,* provides information used by the authorized Forest Service officer or financial analyst to evaluate the financial capability of an applicant to undertake the requested use and to comply with the terms and conditions of an authorization. This form is used primarily for requests to operate ski areas, resorts, and government-owned campgrounds on NFS lands.

18. 16. FS–6500–25, *Request for Verification,* is the form used by an authorized Forest Service officer or financial analyst to: (1) Obtain a release of information from a financial institution to verify the financial capability of an applicant to undertake the requested use, and (2) to comply with the terms and conditions of an authorization. This form is used primarily for requests to operate ski areas, resorts, and government-owned campgrounds on NFS lands.

19. *Response to a Prospectus* (no designated form). When the Forest Service offers a new business opportunity that requires a Special Use authorization, for which there is competitive interest, it is necessary to issue a prospectus. Information provided by applicants in response to a prospectus is used to select the most qualified applicant.

20. Stanislaus FS–2300–1A Tuolumne Wild and Scenic River Permit is the form used by the Forest Service to collect information and to issue temporary permits to use NFS lands for river permit.

21. Stanislaus FS–2300–1B Cherry Creek Self-Registration Permit is the form used by the Forest Service to collect information and to issue temporary permits to use NFS lands for river permit.

Category 2: Special Use Authorizations

1. FS–2700–4, *Special Use Permit,* is the form used by the Forest Service to collect information and to authorize a variety of uses on NFS lands not covered by another form.

2. FS–2700–4b, *Forest Road Special Use Permit,* is the form used by the Forest Service to collect information and to authorize, under FLPMA, the construction and use of an NFS road, typically to access private property within a national forest for commercial

purposes, such as timber hauling or noncommercial purposes such as residential use.

3. FS–2700–4c, *Private Road Special Use Permit,* is the form used by the Forest Service to collect information and to authorize, under FLPMA, the construction and use of a road that is not part of the forest transportation system to access non-Federal land, a mining claim, a mineral leasing area, or other uses of NFS lands.

4. FS–2700–4d, *Temporary Cost Share Agreement Road Special Use Permit,* is the form used by the Forest Service to collect information and to authorize, under FLPMA, the construction, maintenance, and use of a temporary road on NFS lands covered by a cost share agreement to access private property within a national forest for commercial purposes, such as timber harvesting.

5. FS–2700–4h, *Special Use Permit for Campground and Related Granger-Thye Concessions,* is the form used by the Forest Service to collect information and to authorize the operation and maintenance of a government-owned recreation site on NFS lands.

6. FS–2700–4h—*Appendix B, Annual Granger-Thye Fee Offset Agreement,* is used by authorized Forest Service official and the holder to specify the government maintenance, reconditioning, renovation, and improvement used to offset the land use fee for a Campground and Related Granger-Thye Concessions Special Use Permit.

7. FS–2700–4h—*Appendix F, Special Use Permit for Campground and Related Granger-Thye Concessions,* describes the Forest Service's drinking water program and the requirements that apply to holders authorized to operate a federally owned drinking water system.

8. FS–2700–4h—*Appendix G, Granger-Thye Fee Offset Claim Certification,* is used by a holder to provide a record of said holder's direct and indirect costs attributable to a project enumerated in a Granger-Thye Fee Offset Agreement.

9. FS–2700–4i, *Special Use Permit for Outfitting and Guiding,* is the form used by the Forest Service to collect information and authorize the use and occupancy of NFS lands to provide outfitting and guiding services.

10. FS–2700–4j, *Special Use Permit for a Federal Agency's Electric Transmission Facilities,* is the form used by the Forest Service to collect information and authorize the use and occupancy of NFS lands by a Federal agency that owns and operates electric transmission lines and facilities.

11. FS–2700–4—*Shawnee, Special Use Permit for Equestrian Outfitting on the Shawnee National Forest,* is required as part of a litigation settlement for the Shawnee National Forest.

12. FS–2700–5, *Term Special Use Permit,* is the form used by the Forest Service to collect information and authorize long-term use of NFS lands involving privately owned facilities.

13. FS–2700–5a, *Term Special Use Permit for Recreation Residences,* is the form used by the Forest Service to collect information and authorize a privately owned recreation residence on NFS lands.

14. Grand Island–FS–2700–5a, *Term Special Use Permit for Recreation Residences,* is the form used by the Forest Service to collect information and authorize a privately owned recreation residence on Grand Island Recreation Area.

15. FS–2700–5b, *Ski Area Term Special Use Permit,* is the form used by the Forest Service to collect information and authorize ski areas on NFS lands.

16. FS–2700–5c, *Resort/Marina Term Special Use Permit,* is the form used by the Forest Service to collect information and authorize a resort/marina on NFS lands.

17. FS–2700–5d, *Resort Supplement for Outfitting and Guiding,* provides information the Forest Service uses to authorize outfitting and guiding occurring at a resort/marina on NFS lands

18. FS–2700–9a, *Agricultural Irrigation and Livestock Watering System Easement,* is used by the Forest Service to collect information and grant an easement for an agricultural irrigation or a livestock watering system on NFS lands.

19. FS–2700–9b, *Cost Share Easement,* is used by the Forest Service to collect information and authorize, under FRTA, the acquisition, construction, or reconstruction and the maintenance and use of an NFS road that is subject to a cost share agreement. The parties to the cost share agreement grant each other easements within the geographic area covered by the agreement. A cost share easement is for a NFS road and is subject to the cost sharing provisions of the agreement.

20. FS–2700–9c, *Non-Cost Share Easement,* is used by the Forest Service to collect information and authorize, under FRTA, the construction, reconstruction, maintenance, and use of private roads under a cost share agreement. The parties to the cost share agreement grant each other easements within the geographic area covered by the agreement. A non-cost share easement is for a private road (rather than a NFS road) and is not subject to the cost sharing provisions of the agreement.

21. FS–2700–9d, *Public Road Easement,* is used by the Forest Service to collect information and grant easements, under FRTA, to public road authorities, such as States or counties, to construct and maintain public roads that are not part of the Federal Aid Highway System.

22. FS–2700–9e, *Forest Road Easement,* is issued under the National Forest Roads and Trails Act. This form is used by the Forest Service to collect information and to grant an easement, under FRTA, to a party to a cost share agreement, or to another non-Federal landowner who is cooperating in the acquisition, construction, or maintenance of a NFS road. The easement is for acquisition, construction or reconstruction, maintenance, and use of a NFS road that is outside the boundaries of a cost share agreement. At the time the easement is granted, the grantor and the grantee share the costs of acquisition, construction, and reconstruction. After the easement is granted, the grantor and the grantee share only the cost of maintenance.

23. FS–2700–9f, *Private Road Easement,* issued under the National Forest Roads and Trails Act; the Forest Service uses this form to collect information and grant an easement, under FRTA, to a party to a cost share agreement, or to another non-Federal landowner who is cooperating in the acquisition, construction, or maintenance of a NFS road. The easement is for construction or reconstruction, maintenance, and use of a private road that is outside the boundaries of a cost share agreement. Since the easement is for a private rather than a NFS road, the cost of constructing, reconstructing, and maintaining the road are borne by the grantee.

24. FS–2700–9g, *Forest Road Easement,* issued under the Federal Land Policy and Management Act, is used by Forest Service to collect information and grant an easement, under FLPMA, for construction, reconstruction, maintenance, and use of an NFS road, when the grantee is not a party to a cost share agreement for the acquisition, construction, and maintenance of an NFS road, or when the grantee does not meet the requirements for issuance of a forest road easement under FRTA.

25. FS–2700–9h, *Private Road Easement,* issued under the Federal Land Policy and Management Act, is used by the Forest Service to collect information and grant an easement,

under FLPMA, for construction, reconstruction, maintenance, and use of a private road, when the grantee is not a party to a cost share agreement for the acquisition, construction, and maintenance of NFS roads, or when the grantee does not meet the requirements for issuance of a private road easement under FRTA.

26. FS–2700–10b, *Communications Site Lease,* is the form used by the Forest Service to collect information and to authorize a communications use within a designated communications site on NFS lands.

27. FS–2700–10c *(re-numbered from 2700–39), Communications use Permit for Federal Agencies,* is the form used by the Forest Service to collect information and to authorize a communications use within a designated communications site on NFS lands is to be used ONLY for Federal Agencies (other than the Forest Service) who have jurisdiction over the facility.

28. FS–2700–23, *Amendment for Special Use Authorization,* is used by the Forest to collect information and amend an existing special use authorization.

29. FS–2700–25, *Temporary Special Use Permit,* is used by the Forest Service to authorize uses of 1 year or less on NFS lands.

30. FS–2700–26, *Major Category Cost Recovery Agreement,* is used to effectuate cost recovery for special use applications or authorizations involving over 50 hours to process or monitor.

31. FS–2700–26b, *Cost Recovery Master Agreement,* is used by Forest Service officials to effectuate cost recovery for special use applications or authorizations involving multiple phases of development or groups of applications or similar applications for a specified geographic area.

32. FS–2700–27, *Notice to Alaska Native Corporations Regarding Prospectus for Visitor Services,* is used by the Forest Service to collect information and provide notice to Alaska Native Corporations of the issuance of a prospectus to conduct visitor services in Conservation System Units in Alaska. Notification provides the Alaska Native Corporations a chance to request designation as a most directly affected Native Corporation for purposes of competing for the opportunity to conduct visitor services.

33. FS–2700–31, *Electric Transmission Line Easement,* the Forest Service uses this form to collect information and to grant a long-term easement, under FLPMA, for an electric transmission line to a non-federal organization.

34. FS–2700–32, *Permit for Archaeological Investigations,* the Forest Service uses this form to collect information and to grant a permit to a qualified applicant to conduct archeological investigations on or within NFS lands.

Category 3: Annual Financial Information

1. FS–2700–6b, *Recreation Residence Self-Inspection Report,* is the Forest Service uses this form to review and record any modifications made to a recreation residence.

2. FS–2700–7, *Reconciliation of Sales for Fee Calculation,* this form provides information used by the Forest Service to determine land use fees based on sales revenue.

3. FS–2700–8, *Reconciliation of Gross Fixed Assets to Booked Amounts,* the Forest Service uses the information provided on this form to determine land use fees based on the gross fixed assets of the holder.

4. FS–2700–10a, *Telecommunications Facility Inventory,* the Forest Service uses the information provided on this form to determine the rent for a communications facility based on the number of tenants in the facility.

5. FS–2700–19, *Fee Calculation for Concession Permits,* information collected via this form is used by the Forest to determine the land use fee for concession permits under the Graduated Rate Fee System.

6. FS–2700–19a, *Fee Calculation for Ski Area Permits,* this form collects information used by the Forest Service to determine the land use fee for ski area permits under the Ski Fee Act.

7. FS–2700–38, *RUS Certification Form—Telephone Facility,* this form collects information to determine eligibility of fee waiver by the Rural Utility Service.

8. *Business Practices* (no designated form). The holder provides information regarding various business practices, such as basic accounting or financial records, upon request by the authorized officer or as a term and condition of an authorization. In most circumstances, the form used is one customarily used for the type of business involved.

Category 4: Preparing and Updating Operating Plans (No Designated Form)

Special use authorizations may contain a clause requiring the holder to prepare and update an operating plan that governs day-to-day operations of the authorized use. This information is useful to the holder and the Forest Service, because it specifies procedures and policies for conducting the authorized use. Typically, operating plans contain daily operating guidelines, fire abatement and control procedures, monitoring guidelines, maintenance standards, safety and emergency plans, and inspection standards. Operating plans are usually necessary for complex operations, commercial uses, and uses conducted in environmentally sensitive areas.

Category 5: Preparing and Updating Maintenance Plans (No Designated Form)

A permit or easement issued under FLPMA or FRTA may require the holder or grantee to submit and update a road maintenance plan or information necessary for the preparation of a road maintenance plan. A road maintenance plan governs the responsibility of the holder or grantee to perform or pay for maintenance of an NFS road.

Category 6: Compliance Reports and Information Updates

1. FS–2700–1, *Inspection form for Special Uses,* is used to document onsite examination of an authorized activity or facility to assess conditions and inform a compliance review.

2. *Compliance Reports and Information Updates* (no designated form). Special use authorizations may contain a clause requiring the holder to provide the Forest Service with compliance reports, information reports, and other information required by Federal law or to manage NFS lands to ensure adequate protection of national forest resources and public health and safety. Examples of compliance and information updates include dam maintenance inspection reports and logs required by the Reclamation Safety of Dams Act of 1978; the Federal Dam Safety Inspection Act of 1979; and the Dam Safety Act of 1983; documentation that authorized facilities passed safety inspections; documentation showing that the United States is named as an additional insured in an insurance policy issued to a holder; notifications involving a change in ownership of authorized improvements or a change in control of the holder; and documentation of compliance with Title VI of the Civil Rights Act of 1964.

Forest Service

Estimated Annual Burden: 2.9 burden hours per response (this is an average burden per form; this estimated annual burden also includes data from the DOI and USACE.

Type of Respondents: Individuals, Businesses, Non-profit Organizations, and Non-Federal Governmental entities.

Estimated Annual Number of Respondents: 168,728 respondents (this

is a 3-year user rate average as tracked by the Special Use Data System (SUDS); this estimated annual number of respondents also includes data from the DOI and USACE).

Estimated Annual Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 336,463.5 hours (this is an estimation based on a three-year usage rate as tracked by SUDS multiplied by Burden Hours per Form; this estimated annual burden on respondents also includes data from the DOI and USACE).

Department of the Interior—BLM, FWS, NPS and BOR

Estimated Annual Burden: 25 burden hours per response.

Type of Respondents: Individuals, Businesses, Non-profit Organizations, and State and Local and Federal Government.

Estimated Annual Number of Respondents: 5,254.

Estimated Annual Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 131,051 hours.

U.S. Army Corp of Engineers

Estimated Annual Burden: 25 burden hours per response.

Type of Respondents: Individuals, Businesses, Non-profit Organizations, and State and Local and Federal Government.

Estimated Annual Number of Respondents: 32.

Estimated Annual Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 800 hours.

Comment Is Invited

Comment is invited on: (1) Whether this collection of information is necessary for the stated purposes and the proper performance of the functions of the agency, including whether the information will have practical or scientific utility; (2) the accuracy of the agency's estimate of the burden of the 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) ways to minimize the burden of the collection of information on respondents, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission request toward Office of Management and Budget approval.

Greg Smith,

Director, Lands and Realty Management.

[FR Doc. 2020–11615 Filed 5–28–20; 8:45 am]

BILLING CODE 3411–15–P

CIVIL RIGHTS COMMISSION

Sunshine Act Meeting

AGENCY: United States Commission on Civil Rights.

ACTION: Notice of Commission public business meeting.

DATES: Friday June 5, 2020, 10:00 a.m. ET.

ADDRESSES: Meeting to take place by telephone and open to the public by telephone: 1–888–601–3862, Conference ID 992–9363. Computer assisted real-time transcription (CART) will be provided. The web link to access CART (in English) on Friday, June 5, 2020, is *https://www.streamtext.net/player?event=USCCR*. Please note that CART is text-only translation that occurs in real time during the meeting and is not an exact transcript.

FOR FURTHER INFORMATION CONTACT: Zakee Martin: (202) 376–7700; *publicaffairs@usccr.gov*.

Meeting Agenda

I. Approval of Agenda

II. Business Meeting

A. Presentation by Alexandra Korry, Chair of New York Advisory Committee on the Committee's report, *Education Equity in New York: A Forgotten Dream.*

B. Discussion and vote on Commission Advisory Committees
- Chair of North Carolina Advisory Committee
- Chair of Maine Advisory Committee
- New York Advisory Committee
- Washington Advisory Committee

C. Discussion and vote on project planning materials in support of Commission short-term projects on civil rights impacts of the COVID–19 pandemic

D. Discussion and vote on Administrative Instruction 5–7, Advisory Committee Meetings and Reports

E. Update from Staff Director on virtual briefing

F. Management and Operations
- Staff Director's Report

III. Adjourn Meeting

Dated: May 26, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–11663 Filed 5–27–20; 11:15 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Federal Consistency Appeal by WesternGeco of North Carolina Objection

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of extension of time to issue a decision.

SUMMARY: This announcement provides notice that the deadline for issuing a decision has been extended by 15 days in the administrative appeal filed with the Department of Commerce (Department) by WesternGeco requesting that the Secretary of Commerce (Secretary) override an objection by the North Carolina Division of Coastal Management to a consistency certification for a proposed project to conduct a marine Geological and Geophysical seismic survey in the Atlantic Ocean.

DATES: The new deadline for issuing a decision on WesternGeco's federal consistency appeal of North Carolina's objection is extended to June 15, 2020.

ADDRESSES: NOAA has provided access to publicly available materials and related documents comprising the appeal record on the following website: *http://www.regulations.gov/#!docketDetail;D=NOAA-HQ-2019-0089*.

FOR FURTHER INFORMATION CONTACT: For questions about this Notice, contact Martha McCoy, NOAA Office of General Counsel, Oceans and Coasts Section, 1305 East-West Highway, Room 6111, Silver Spring, MD 20910, (301) 713–7391, *martha.mccoy@noaa.gov*.

SUPPLEMENTARY INFORMATION:

I. Notice of Appeal

On September 20, 2019, the Secretary received a ''Notice of Appeal'' filed by WesternGeco pursuant to the Coastal Zone Management Act of 1972 (CZMA), 16 U.S.C. 1451 *et seq.,* and implementing regulations found at 15 CFR part 930, subpart H. The ''Notice of Appeal'' is taken from an objection by the North Carolina Division of Coastal Management to a consistency certification for a proposed project to

conduct a marine Geological and Geophysical seismic survey in the Atlantic Ocean. This matter constitutes an appeal of an ''energy project'' within the meaning of the CZMA regulations, *see* 15 CFR 930.123(c).

Under the CZMA, the Secretary may override the North Carolina Division of Coastal Management's objection on grounds that the project is consistent with the objectives or purposes of the CZMA, or is necessary in the interest of national security. To make the determination that the proposed activity is ''consistent with the objectives or purposes of the CZMA,'' the Department must find that: (1) The proposed activity furthers the national interest as articulated in sections 302 or 303 of the CZMA, in a significant or substantial manner; (2) the national interest furthered by the proposed activity outweighs the activity's adverse coastal effects, when those effects are considered separately or cumulatively; and (3) no reasonable alternative is available that would permit the proposed activity to be conducted in a manner consistent with the enforceable policies of the applicable coastal management program. 15 CFR 930.121. To make the determination that the proposed activity is ''necessary in the interest of national security,'' the Secretary must find that a national defense or other national security interest would be significantly impaired if the proposed activity is not permitted to go forward as proposed. 15 CFR 930.122.

On March 30, 2020, NOAA published a **Federal Register** Notice announcing closure of the appeal decision record. 85 FR 17539. Under the CZMA, a final decision on the appeal must be issued no later than 60 days after notice announcing closure of the decision record is published. 16 U.S.C. 1465(b)(3). This deadline may be extended, however, by publishing (within the 60-day period) a subsequent notice explaining why a decision cannot be issued within that time frame. 16 U.S.C. 1465(c)(1). In that event, a final decision must be issued no later than 15 days after the date of publication of the subsequent notice. 16 U.S.C. 1465(c)(2).

This announcement provides notice that the deadline for issuing a decision on this appeal has been extended by 15 days. The additional time is needed to complete a review of the record and reach a decision. A decision on the federal consistency appeal will be issued no later than June 15, 2020.

(Authority Citation: 16 U.S.C. 1465(c); 15 CFR 930.130(b))

Adam Dilts,

Chief, Oceans and Coasts Section, NOAA Office of General Counsel.

[FR Doc. 2020–11341 Filed 5–28–20; 8:45 am]

BILLING CODE 3510–JE–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–P–2020–0028]

Grant of Interim Extension of the Term of U.S. Patent No. 9,364,354; Reducer®

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of interim patent term extension.

SUMMARY: The United States Patent and Trademark Office has issued an order granting interim extension for a one-year interim extension of the term of U.S. Patent No. 9,364,354.

FOR FURTHER INFORMATION CONTACT: Ali Salimi by telephone at (571) 272–0909; by mail marked to his attention and addressed to the Commissioner for Patents, Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313–1450; by fax marked to his attention at (571) 273–0909; or by email to *ali.salimi@uspto.gov*.

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for interim periods of up to one year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On May 21, 2020, Neovasc Medical Ltd., the patent owner of record, timely filed an application under 35 U.S.C. 156(d)(5) for an interim extension of the term of U.S. Patent No. 9,364,354. The patent claims the catheter implantable device, Reducer®. The application for patent term extension indicates that a Premarket Approval Application (PMA) P190035 was submitted to the Food and Drug Administration (FDA) on December 31, 2019.

Review of the patent term extension application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. 156, and that the patent should be extended for one year as required by 35 U.S.C. 156(d)(5)(B). Because the regulatory review period will continue beyond the original expiration date of the patent, June 6, 2020, interim extension of the patent term under 35 U.S.C. 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. 156(d)(5) of the term of U.S. Patent No. 9,364,354 is granted for a period of one year from the original expiration date of the patent.

Robert Bahr,

Deputy Commissioner for Patent Examination Policy, United States Patent and Trademark Office.

[FR Doc. 2020–11626 Filed 5–28–20; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Native American Tribal Insignia Database

The United States Patent and Trademark Office (USPTO) will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The USPTO invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps the USPTO assess the impact of its information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on March 16, 2020 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: United States Patent and Trademark Office, Department of Commerce.

Title: Native American Tribal Insignia Database

OMB Control Number: 0651–0048.

Form Number(s): None.

Type of Request: Extension and revision of a currently approved information collection.

Number of Respondents: 5 respondents.

Average Hours per Response: The USPTO estimates that a recognized Native American tribe will require an average of 1 hour to complete a request to record an official insignia, including

time to prepare the appropriate documents and submit the completed request to the USPTO.

Burden Hours: 5 hours.

Estimated Total Annual Non-Hour Respondent Cost Burden: $38.

Needs and Uses: The Trademark Law Treaty Implementation Act of 1998 (Pub. L. 105–330, 302, 112 Stat. 3071) required the USPTO to study issues surrounding the protection of the official insignia of federally and state-recognized Native American tribes under trademark law. At the direction of Congress, the USPTO created a database containing the official insignia of recognized Native American tribes. This database is available at the USPTO's website, as part of the USPTO's Trademark Electronic Search System (TESS). This information collection is used by the USPTO to enter an official insignia submitted by a federally or state-recognized Native American tribe into the database.

The USPTO database of official tribal insignias provides evidence of what a federally or state-recognized Native American tribe considers to be its official insignia. Section 2(a) of the Trademark Act, 15 U.S.C. 1052(a), disallows the registration of marks that falsely suggest a connection with a non-sponsoring person or institution, including a Native American tribe. The database thereby assists trademark examining attorneys in their examination of applications for trademark registration by serving as a reference for determining the registrability of a mark that may falsely suggest a connection to the official insignia of a Native American tribe. The entry of an official insignia into the database does not confer any rights to the tribe that submitted the insignia, and entry is not the legal equivalent of registering the insignia as a trademark under 15 U.S.C. 1051 *et seq.*

Frequency: On occasion.

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

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

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *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 and entering either the title of the information collection or the OMB Control Number 0651–0048.

Further information can be obtained by:

- *Email: InformationCollection@uspto.gov*. Include ''0651–0048 copy request'' in the subject line of the message.
- *Mail:* Kimberly Hardy, Office of the Chief Administrative Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

Kimberly Hardy,

Information Collections Officer, Office of the Chief Administrative Officer, United States Patent and Trademark Office.

[FR Doc. 2020–11617 Filed 5–28–20; 8:45 am]

BILLING CODE 3510–16–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to and deletions from the Procurement List.

SUMMARY: This action adds products to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes products and services from the Procurement List previously furnished by such agencies.

DATES: *Date added to and deleted from the Procurement List:* June 28, 2020.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: Michael R. Jurkowski, Telephone: (703) 603–2117, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov*.

SUPPLEMENTARY INFORMATION:

Additions

On 4/24/2020, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed additions to the Procurement List. This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the products and impact of the additions on the current or most recent contractors, the Committee has determined that the products listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products to the Government.

2. The action will result in authorizing small entities to furnish the products to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products proposed for addition to the Procurement List.

End of Certification

Accordingly, the following products are added to the Procurement List:

Products

NSN(s)—Product Name(s):
MR 13030—Vegetable Chopper
MR 13047—Container, Leakproof, On-the-Go, Clear, Lunch
MR 13048—Container, Leakproof, On-the-Go, Clear, Salad

Mandatory Source of Supply: Cincinnati Association for the Blind, Cincinnati, OH

Contracting Activity: Military Resale-Defense Commissary Agency

Deletions

On 4/24/2020, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List. This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3.

After consideration of the relevant matter presented, the Committee has determined that the products and services listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the

products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products and services deleted from the Procurement List.

End of Certification

Accordingly, the following products and services are deleted from the Procurement List:

Products

NSN(s)—Product Name(s):
6510–00–200–3185—Bandage, Gauze, Compressed, Camouflaged, 3 in x 6 yds.
6510–00–083–5573—Dressing, First Aid, Field, White
6510–00–201–1755—Bandage, Muslin, Compressed, Olive Drab Green, Camouflaged, 37″ x 37″ x 52″
6510–00–201–7680—Compress and Skullcap, Head Dressing
6510–00–159–4883—Dressing, First Aid, Field, Camouflaged, Pad
6510–00–201–7425—Dressing, First Aid, Field, Camouflaged 11¾″ x 11¾″
6510–00–201–7430—Dressing, First Aid, Field, Camouflaged 7¾″ x 7¼″
6510–00–200–3075—Compress and Bandage, Camouflaged, 2 in x 2 in
6510–00–200–3080—Compress and Bandage, Camouflaged, 4 in x 4 in
6510–00–200–3180—Bandage, Gauze, Compressed, Camouflaged, 2 in x 6 yds
6510–00–200–3190—Bandage, Gauze, Compressed, Camouflaged, 4 in by 6 yds
Mandatory Source of Supply: Elwyn, Aston, PA
Contracting Activity: DLA TROOP SUPPORT, PHILADELPHIA, PA

Services

Service Type: Reprographics
Mandatory for: Department of Energy, Washington, DC
Mandatory Source of Supply: Sinai Hospital of Baltimore (Vocational Services Program), Baltimore, MD
Contracting Activity: ENERGY, DEPARTMENT OF, HEADQUARTERS PROCUREMENT SERVICES

Service Type: Janitorial/Custodial
Mandatory for: MICC, West Point, USMA West Point, Sherman (Bldg. 738) & Lee Barracks (Bldg. 740), West Point Academy, West Point, NY
Mandatory Source of Supply: Access: Supports for Living Inc., Middletown, NY
Contracting Activity: DEPT OF THE ARMY, W6QM MICC–WEST POINT

Service Type: Administrative Services
Mandatory for: U.S. Department of the Treasury, Office of Technical Assistance, 740 15th Street NW, 4th Floor, Washington, DC
Mandatory for: Saudi-Arabian Joint Commission Office, Washington, DC
Mandatory Source of Supply: ServiceSource, Inc., Oakton, VA
Contracting Activity: DEPARTMENTAL OFFICES, NATIONAL OFFICE—DO OTPS/TOPS

Michael R. Jurkowski,

Deputy Director, Business & PL Operations.

[FR Doc. 2020–11558 Filed 5–28–20; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID: USAF–2020–HQ–0010]

Proposed Collection; Comment Request

AGENCY: The Office of the Secretary of the Air Force, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* Air Force Research Laboratory/Air Force Office of Scientific Research (AFRL/AFOSR) is requesting an extension of an information collection to evaluate and award Summer Faculty Fellowships and seeks public comment on this action. After obtaining and considering public comment, AFOSR, will prepare the submission requesting that the Office of Management and Budget (OMB) approve extension of this collection for no longer than 3 years. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by July 28, 2020.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information. Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Air Force Office of Scientific Research, ATTN: Raheem A. Lawal, AFOSR/RTA, 875 North Randolph Street, Suite 325, Room 3112, Arlington, VA 22203–1768, or call AFOSR/RTA, at 703–696–7313.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Notice of Intent to Extend Approval to Collect Information for the AFRL/AFOSR Summer Faculty Fellowship Program (SFFP) and Associated acceptance forms; OMB Control Number 0701–0155.

Needs and Uses: The information collection requirement is necessary to identify some of the nation's most talented scientific personnel for award of fellowships at Air Force research activities. Summer fellowships provide research opportunities for 8–14 weeks at an Air Force research site.

Affected Public: Individuals and households.

Annual Burden Hours: 75 hours.

Number of Respondents: 300.

Responses per Respondent: 1.

Annual Responses: 300.

Average Burden per Response: 15 minutes.

Frequency: Annually.

Respondents are Professors, Associate Professors, and Assistant Professors, undergraduate and graduate students desiring to conduct stimulating research projects and activities at Air Force research sites. The on-line, electronic application process provides information necessary for evaluation and selection of researchers. Associated award forms provide required information for direct deposit of stipends and reporting to the IRS.

Dated: May 22, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–11529 Filed 5–28–20; 8:45 am]

BILLING CODE 5001–05–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID: USAF–2020–HQ–0008]

Proposed Collection; Comment Request

AGENCY: Office of the Assistant Secretary of the Air Force, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Assistant Secretary of the Air Force announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by July 28, 2020.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Angela James, Office of Information Management, DoD, at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil* or call 571–372–7574.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Verification of Graduation; AFRS Form 1413, AF Form 215; OMB Control Number 0701–0080.

Needs and Uses: Title 10, U.S.C. 9411 provides for the commissioning of officers in the Armed Forces: Air Force Manual 36–2032 implements the policy. Air Force Recruiting Service (AFRS) SOPG, Section H, provides procedures. Air Force Instruction 36–2105 provides the policy for age limitations for applying for flying training, whether through a commissioning source or for commissioned officers who wish to crosstrain and apply for flying training.

AFRS applicants use AFRS Form 1413 as part of each application that is submitted for consideration by the Air Force Officer Training School (OTS) selection board.

Air Force Personnel Center (AFPC) uses the AF Form 215 as part of each application that is submitted for consideration by commissioned officers who wish to attend undergraduate flying training (UFT).

Affected Public:

AFRS Form 1413: Individuals and Households.

AF Form 215: Individuals and Households.

Annual Burden Hours:

AFRS Form 1413: 250 hours.

AF Form 215: 125 hours.

Total Burden: 375 hours.

Number of Respondents:

AFRS Form 1413: 500.

AF Form 215: 250.

Total Respondents: 750.

Responses per Respondent:

AFRS Form 1413: 1.

AF Form 215: 1.

Total Responses per Respondent: 1.

Annual Responses:

AFRS Form 1413: 500.

AF Form 215: 250.

Total Annual Responses: 750.

Average Burden per Response:

AFRS Form 1413: 30 minutes.

AF Form 215: 30 minutes.

Total Average Burden per Responses: 30 minutes.

Frequency: On occasion.

Dated: May 22, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–11527 Filed 5–28–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID: USAF–2020–HQ–0007]

Proposed Collection; Comment Request

AGENCY: Department of the Air Force, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Department of the Air Force, Director of Bases, Ranges, and Airspace, Directorate of Operations, Deputy Chief of Staff, Operations, Plans and Requirements, announces a proposed reinstatement of a public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by July 28, 2020.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on

any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the HQ USAF/A3OJ, 112 Luke Avenue, Suite 340, JBAB DC, 20032–6400, ATTN: Mr. James Rogers, or call 202–404–7886.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Civil Aircraft Landing Permit System; DD Form 2400, DD Form 2401, DD Form 2402; OMB Number 0701–0050.

Needs and Uses: The information collection requirement is necessary to ensure that the security and operational integrity of military airfields are maintained; to identify the aircraft operator and the aircraft to be operated; to avoid competition with the private sector by establishing the purpose for use of military airfields; and to ensure the U.S. government is not held liable if the civil aircraft becomes involved in an accident or incident while using military airfields, facilities, and services.

Affected Public:

DD 2400: Businesses and Private Sector.
DD 2401: Individuals and Households.
DD 2402: Individuals and Households.

Annual Burden Hours:

DD 2400: 300 hours.
DD 2401: 300 hours.
DD 2402: 300 hours.
Total Annual Burden Hours: 900.

Number of Respondents:

DD 2400: 1,800.
DD 2401: 1,800.
DD 2402: 1,800.
Total Number of Respondents: 5,400.

Responses per Respondent:

DD 2400: 1.
DD 2401: 1.
DD 2402: 1.

Average Burden per Response:

DD 2400: 10 minutes.
DD 2401: 10 minutes.
DD 2402: 10 minutes.
Total Average Burden per Response: 10 minutes.

Frequency: On occasion.

Respondents are civil aircraft owners/operators who are requesting authorized landings at DoD airfields. These requestors are required to submit the indicated DD Forms (2400, 2401, and 2402). The completed forms included are maintained by HQ USAF/A3OJ for 2 years for any required review. These forms ensure only authorized civil aircraft owners/operators are authorized access to DoD airfields.

Dated: May 22, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–11526 Filed 5–28–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

Draft Environmental Impact Statement and Draft Finding of No Practicable Alternative for the Proposed Heavy Off-Road Mounted Maneuver Training Area at Fort Benning, Georgia

AGENCY: Department of the Army, DoD.

ACTION: Notice of availability.

SUMMARY: The Department of the Army (Army) announces the availability of the Draft Environmental Impact Statement (EIS) for the proposed Heavy Off-Road Mounted Maneuver Training Area (HOMMTA) at Fort Benning, Georgia. In accordance with the National Environmental Policy Act (NEPA), the Draft EIS analyzes the potential environmental and socioeconomic impacts, and recommends related mitigation measures, associated with constructing, operating, and maintaining a HOMMTA of at least 2,400 contiguous acres at Fort Benning to support off-road mounted maneuver (Proposed Action). The Proposed Action would support the Maneuver Center of Excellence (MCoE) in its mission to train the maneuver forces of the Army and would increase the total amount of heavy off-road maneuver training area on Fort Benning, enabling Fort Benning to conduct realistic training in accordance with current Army training requirements. The Proposed Action would provide a training area to meet existing training needs; it would not result in additional Soldiers, traffic, or any training off of the Installation. Training land development would occur over a 2- to 3-year period; development would primarily include vegetation removal and the construction of tank trails, culverted water crossings, and road upgrades, as well as burying existing overhead utilities. As feasible, buffers would be used to protect environmentally sensitive resources such as streams, wetlands, cemeteries, and archaeological sites. A Draft Finding of No Practicable Alternative (FONPA) addressing potential impacts on wetlands and 100-year floodplains is also available in the Draft EIS for comment.

DATES: Comments must be received by July 13, 2020 to be considered in the preparation of the Final EIS.

ADDRESSES: Please send written comments to Fort Benning Environmental Management Division, Attn: NEPA Program Manager, 6650 Meloy Drive, Building 6, Room 309, Fort Benning, Georgia 31905–5122, or email comments to *john.e.brown12.civ@mail.mil*.

FOR FURTHER INFORMATION CONTACT: Please contact Mr. John Brown, Fort Benning Environmental Management Division, at (706) 545–7549 between 9 a.m. and 4 p.m. ET. Fort Benning has also established a web page that contains information updates and background on the HOMMTA and the EIS at *https://www.benning.army.mil/Garrison/DPW/EMD/HOMMTA/*.

SUPPLEMENTARY INFORMATION: Fort Benning plays a critical role in supporting the Army's overarching mission. As the Army's MCoE, the home of the Army's Armor and Infantry Schools, Fort Benning must support the institutional training of Infantry and Armor Soldiers and leaders. The institutional training conducted at Fort Benning provides Army leaders with the opportunity to respond to a wide variety of situations that they can expect to encounter on the modern battlefield. Fort Benning is also home to several deployable units that conduct off- road mounted maneuver training, including the 1st Security Force Assistance Brigade, Task Force 1–28 Infantry, and elements of the 75th Ranger Regiment.

Fort Benning must be able to train and develop highly skilled and cohesive units capable of conducting operations across the full spectrum of potential conflicts. Inherent in and vital to training Infantry and Armor Soldiers and leaders properly is the requirement to provide sufficient heavy off-road mounted maneuver training area. Currently, the only training area at Fort Benning suitable for heavy off-road mounted maneuver training is the Good Hope Maneuver Training Area (GHMTA).

Since the initial development of the GHMTA, the Army's training strategy has changed to ''cross-domain movement and maneuver'' that requires additional contiguous area for heavy off-road maneuver. In an attempt to accommodate this requirement, the Army continued to improve the off-road maneuver area within the GHMTA. Despite these improvements, the existing GHMTA landscape contains slopes, streams, wetlands, and other limitations that cannot support the increased maneuver training

requirements of the MCoE and Fort Benning's tenant units. As such, Fort Benning proposes to construct a new HOMMTA with sufficient contiguous area to enable all units and courses to complete required cross-domain movement and maneuver training.

The Draft EIS analyzes the potential environmental and socioeconomic impacts associated with the Proposed Action, including direct, indirect, and cumulative effects. Mitigation of adverse effects through avoidance and environmentally sensitive design, such as establishment of buffers, would be used to avoid impacts to sensitive resources to the maximum extent practicable. Where these efforts are not sufficient to avoid adverse effects, the Draft EIS recommends additional mitigation measures that the Army may implement to further reduce identified adverse impacts.

In support of the EIS, the Army is also preparing other studies, analyses, and permit applications to meet Federal requirements, such as Section 7 of the Endangered Species Act, Sections 401 and 404 of the Clean Water Act (CWA), and Section 106 of the National Historic Preservation Act.

The Army identified three reasonable Action Alternatives that would meet the purpose of and need for the Proposed Action; these three Action Alternatives (*i.e.,* three distinct locations on Fort Benning where a HOMMTA could be constructed) are analyzed in detail in the Draft EIS.

1. Alternative 1 (Preferred Alternative): Northern Mounted Maneuver Training Area Alternative: This alternative includes approximately 4,724 acres and is located adjacent to and east of the current Northern Maneuver training Area and west of and near Fort Benning's Digital Multi-Purpose Range Complex (DMPRC).

Of the Action Alternatives, Alternative 1 would provide the most preferable size and configuration to enable high-quality heavy off-road mounted maneuver training. Accordingly, the Army has identified Alternative 1 as the Preferred Alternative to implement the Proposed Action.

2. Alternative 2: Red Diamond Alternative: This alternative includes approximately 3,744 acres and is located south of the Southern Maneuver Training Area (SMTA) near the Installation's southern boundary.

3. Alternative 3: Eastern Boundary Alternative: This alternative includes approximately 2,405 acres and is located between the northern dudded impact area and the Installation's eastern boundary.

The Army also carried forward the No Action Alternative for detailed analysis in the Draft EIS. While the No Action Alternative would not satisfy the purpose of or need for the Proposed Action, this Alternative was retained to provide a comparative baseline against which to analyze the effects of the Action Alternatives as required under the Council on Environmental Quality's NEPA Regulation.

Resource areas analyzed in the Draft EIS include: Land use (recreation), air quality, noise, soils and topography, water resources, biological resources, cultural resources, socioeconomics, infrastructure, and hazardous and toxic materials and waste.

Based on the analysis presented in the Draft EIS, potentially significant adverse impacts could occur to biological resources (*i.e.,* from disturbance of unique ecological areas). Impacts to all other resource areas would be less-than-significant adverse (*i.e.,* negligible, minor, or moderate), or beneficial. Recommended mitigation measures are presented in the Draft EIS to reduce potential adverse effects.

All Action Alternatives for the Proposed Action may adversely impact wetlands and/or 100-year floodplains. Accordingly, the Army has also prepared a Draft FONPA to comply with Executive Order (E.O.) 11988, *Floodplain Management,* and E.O. 11990, *Protection of Wetlands.* As described in the Draft EIS, environmental protection measures (*e.g.,* buffers from heavy maneuver training) and regulatory compliance measures (*e.g.,* permitting under Sections 401 and 404 of the CWA) would be implemented to minimize adverse impacts on these resources.

Government agencies, Native American Tribes, and the public are invited to review and comment on the Draft EIS. The public comment period begins with the publication of this Notice of Availability in the **Federal Register** and will last for 45 days. The Draft EIS and Draft FONPA are available to the public on the HOMMTA web page at *https://www.benning.army.mil/Garrison/DPW/EMD/HOMMTA/*. The comment period will also include a public meeting that will provide an opportunity for the public to comment about the Proposed Action, Alternatives, and environmental impact analysis. Due to the COVID–19 Pandemic and the need to maintain social distancing, Fort Benning will host the public meeting by telephone. Specific details of the telephone meeting will be announced in local media and on the HOMMTA website, *https://www.benning.army.mil/Garrison/DPW/EMD/HOMMTA/*. The HOMMTA Draft EIS and meeting materials will be provided online at *https://fortbenning.consultation.ai/*. If you cannot access the meeting materials online, please submit a request to Mr. John Brown at *john.e.brown12.civ@mail.mil* or by mail to address provided above so materials can be sent to you. Please ensure your request is postmarked no later than June 15, 2020 so that Fort Benning can mail the meeting materials prior to the telephone meeting date. Later requests for documents will be accepted, but the requests may not be fulfilled prior to the HOMMTA telephone meeting date.

Following the public comment period, the Army will consider all public comments and prepare a Final EIS and Record of Decision prior to making any decision regarding the Proposed Action. Comments must be received or postmarked by July 13, 2020 to be considered during preparation of the Final EIS.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2020–11540 Filed 5–28–20; 8:45 am]

BILLING CODE 5061–AP–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DOD–2020–OS–0054]

Proposed Collection; Comment Request

AGENCY: Office of the Chief Information Officer, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Chief Information Officer announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by July 28, 2020.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Ms. Angela James, Office of Information Management, DoD, at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil* or call 571–372–7574.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Defense Industrial Base (DIB) Cybersecurity (CS) Program Point of Contact Information; OMB Control Number 0704–0490.

Needs and Uses: DoD's Defense Industrial Base (DIB) Cybersecurity (CS) Program enhances and supports DIB CS participants' capabilities to safeguard DoD information that resides on, or transits, DIB unclassified information systems. The operational implementation of this Program requires DoD to collect, share, and manage point of contact (POC) information for Program administration and management purposes. The Government will collect typical business POC information from all DIB CS participants to facilitate communication and share cyber threat information. To implement and execute this Program within their companies, DIB CS participants provide POC information to DoD during the application process to join the Program. This information includes the names, company names and mailing address, work divisions/groups, work email addresses, and work telephone numbers of company-identified POCs. DIB CS Program POCs include the Chief Executive Officer (CEO), Chief Information Officer (CIO), Chief Information Security Officer (CISO), General Counsel, Corporate or Facility Security Officer, and the Chief Privacy Officer, or their equivalents, as well as those administrative, policy, technical staff, and personnel designated to interact with the Government in executing the DIB CS Program (*e.g.,* typically 3–10 company designated POCs). After joining the Program, DIB CS participants provide updated POC information to DoD when personnel changes occur.

Affected Public: Individuals and Households, Private Sector and Small Businesses.

Annual Burden Hours: 2,530 hours.

Number of Respondents: 7,590.

Responses per Respondent: 1.

Annual Responses: 7,590.

Average Burden per Response: 20 minutes.

Frequency: On occasion.

Dated: May 26, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–11544 Filed 5–28–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2020–OS–0003]

Submission for OMB Review; Comment Request

AGENCY: Office of the Chief Management Officer, Department of Defense (DoD).

ACTION: 30-day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by June 29, 2020.

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.

FOR FURTHER INFORMATION CONTACT: Angela James, 571–372–7574, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Scooter Registration Form, SD Form 0836; OMB Control Number 0704–XXXX.

Type of Request: New.

Number of Respondents: 33.

Responses per Respondent: 1.

Annual Responses: 33.

Average Burden per Response: 2 hours.

Annual Burden Hours: 66.

Needs and Uses: Washington Headquarters Services (WHS) needs to collect this information to be able to provide reasonable accommodations to WHS and WHS-serviced organizations' personnel needing mobility assistance for individuals with disabilities.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela James.

Requests for copies of the information collection proposal should be sent to Ms. James at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: May 22, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–11535 Filed 5–28–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2020–OS–0020]

Submission for OMB Review; Comment Request

AGENCY: Defense Contract Management Agency, Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of

information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by June 29, 2020.

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.

FOR FURTHER INFORMATION CONTACT: Angela James, 571–372–7574, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil*.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Request for Approval for Qualification Training and Approval of Contractor Flight Crewmember; DD Form 2627, DD Form 2628, DD Form 3062; OMB Control Number 0704–0347.

Type of Request: Revision.

Number of Respondents: 150.

Responses per Respondent:

DD Form 2627: 2.
DD Form 2628: 2.
DD Form 3062: 52.

Annual Responses:

DD Form 2627: 300.
DD Form 2628: 300.
DD Form 3062: 7,800.
Total: 8,400.

Average Burden per Response:

DD Form 2627: 30 minutes.
DD Form 2628: 30 minutes.
DD Form 3062: 1 hour.

Annual Burden Hours:

DD Form 2627: 150 hours.
DD Form 2628: 150 hours.
DD Form 3062: 7,800 hours.
Total: 8,100 hours.

Needs and Uses: This is a request for OMB approval of updated versions of previously approved collections (for DD Form 2627 and 2628) for which approval has expired, and for OMB approval of new collection (DD Form 3062) which replaces the Defense Contract Management Agency (DCMA) Form 644. The requirements to have government approval of contract flight crewmembers and contract flights is in Defense Contract Management Command Instruction (DCMA INST) 8210.1, Contractor's Ground and Flight Operations, Chapter 4. The contractor provides information on contractor personnel to the government. The government approves the contractor's request for aircrew training and eventually, approval for contractor personnel to operate and fly government aircraft. The government also approves all flights under contract.

Affected Public: Individuals or households.

Frequency:

DD Form 2627: Semi-annually.
DD Form 2628: Semi-annually.
DD Form 3062: Weekly.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DoD Clearance Officer: Ms. Angela James.

Requests for copies of the information collection proposal should be sent to Ms. James at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil*.

Dated: May 22, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–11532 Filed 5–28–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Revised Non-Foreign Overseas Per Diem Rates

AGENCY: Defense Human Resources Activity, Department of Defense (DoD).

ACTION: Notice of revised per diem rates in non-foreign areas outside the Continental U.S.

SUMMARY: Defense Human Resources Activity publishes this Civilian Personnel Per Diem Bulletin Number 313. Bulletin Number 313 lists current per diem rates prescribed for reimbursement of subsistence expenses while on official Government travel to Alaska, Hawaii, the Commonwealth of Puerto Rico, and the possessions of the United States. The Fiscal Year (FY) 2020 per diem rate review for Puerto Rico resulted in lodging, meal and incidental rate changes in certain locations.

DATES: The updated rates take effect June 1, 2020.

FOR FURTHER INFORMATION CONTACT: Mr. Scott Laws, 571–372–1282.

SUPPLEMENTARY INFORMATION: This document notifies the public of revisions in per diem rates prescribed by the Per Diem, Travel and Transportation Allowance Committee for travel to non-foreign areas outside the continental United States. The FY 2020 per diem rate review for Puerto Rico resulted in lodging, meal and incidental rate changes in certain locations. Bulletin Number 313 is published in the **Federal Register** to ensure that Government travelers outside the Department of Defense are notified of revisions to the current reimbursement rates.

If you believe the lodging, meal or incidental allowance rate for a locality listed in the following table is insufficient, you may request a rate review for that location. For more information about how to request a review, please see the Defense Travel Management Office's Per Diem Rate Review Frequently Asked Questions (FAQ) page at *https://www.defensetravel.dod.mil/site/faqraterev.cfm*.

Dated: May 26, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

State or territory	Locality	Season start	Season end	Lodging	M&IE	Total per diem	Effective date
ALASKA	[OTHER]	01/01	12/31	161	113	274	06/01/2019
ALASKA	ADAK	01/01	12/31	161	117	278	06/01/2019
ALASKA	ANCHORAGE [INCL NAV RES]	05/01	08/31	229	125	354	06/01/2019
ALASKA	ANCHORAGE [INCL NAV RES]	09/01	04/30	199	125	324	06/01/2019
ALASKA	BARROW	05/15	09/14	320	129	449	06/01/2019
ALASKA	BARROW	09/15	05/14	265	129	394	06/01/2019
ALASKA	BARTER ISLAND LRRS	01/01	12/31	161	113	274	06/01/2019

State or territory	Locality	Season start	Season end	Lodging	M&IE	Total per diem	Effective date
ALASKA	BETHEL	01/01	12/31	219	101	320	06/01/2019
ALASKA	BETTLES	01/01	12/31	161	113	*274	06/01/2019
ALASKA	CAPE LISBURNE LRRS	01/01	12/31	161	113	274	06/01/2019
ALASKA	CAPE NEWENHAM LRRS	01/01	12/31	161	113	274	06/01/2019
ALASKA	CAPE ROMANZOF LRRS	01/01	12/31	161	113	274	06/01/2019
ALASKA	CLEAR AB	01/01	12/31	161	113	274	06/01/2019
ALASKA	COLD BAY	01/01	12/31	161	113	274	06/01/2019
ALASKA	COLD BAY LRRS	01/01	12/31	161	113	274	06/01/2019
ALASKA	COLDFOOT	01/01	12/31	161	93	254	06/01/2019
ALASKA	COPPER CENTER	01/01	12/31	161	115	276	06/01/2019
ALASKA	CORDOVA	01/01	12/31	140	106	246	06/01/2019
ALASKA	CRAIG	05/01	09/30	139	94	233	06/01/2019
ALASKA	CRAIG	10/01	04/30	109	94	203	06/01/2019
ALASKA	DEADHORSE	01/01	12/31	120	113	*233	06/01/2019
ALASKA	DELTA JUNCTION	01/01	12/31	161	101	262	06/01/2019
ALASKA	DENALI NATIONAL PARK	05/17	09/17	189	98	287	06/01/2019
ALASKA	DENALI NATIONAL PARK	09/18	05/16	139	98	237	06/01/2019
ALASKA	DILLINGHAM	05/01	09/30	275	113	388	06/01/2019
ALASKA	DILLINGHAM	10/01	04/30	230	113	343	06/01/2019
ALASKA	DUTCH HARBOR-UNALASKA	01/01	12/31	161	129	290	06/01/2019
ALASKA	EARECKSON AIR STATION	01/01	12/31	146	74	220	06/01/2019
ALASKA	EIELSON AFB	05/16	09/15	154	100	254	06/01/2019
ALASKA	EIELSON AFB	09/16	05/15	75	100	175	06/01/2019
ALASKA	ELFIN COVE	01/01	12/31	161	113	274	06/01/2019
ALASKA	ELMENDORF AFB	05/01	08/31	229	125	354	06/01/2019
ALASKA	ELMENDORF AFB	09/01	04/30	199	125	324	06/01/2019
ALASKA	FAIRBANKS	05/16	09/15	154	100	254	06/01/2019
ALASKA	FAIRBANKS	09/16	05/15	75	100	175	06/01/2019
ALASKA	FORT YUKON LRRS	01/01	12/31	161	113	274	06/01/2019
ALASKA	FT. GREELY	01/01	12/31	161	101	262	06/01/2019
ALASKA	FT. RICHARDSON	05/01	08/31	229	125	354	06/01/2019
ALASKA	FT. RICHARDSON	09/01	04/30	199	125	324	06/01/2019
ALASKA	FT. WAINWRIGHT	05/16	09/15	154	100	254	06/01/2019
ALASKA	FT. WAINWRIGHT	09/16	05/15	75	100	175	06/01/2019
ALASKA	GAMBELL	01/01	12/31	161	113	274	06/01/2019
ALASKA	GLENNALLEN	01/01	12/31	161	115	276	06/01/2019
ALASKA	HAINES	01/01	12/31	107	113	220	06/01/2019
ALASKA	HEALY	06/01	08/31	189	98	287	06/01/2019
ALASKA	HEALY	09/01	05/31	139	98	237	06/01/2019
ALASKA	HOMER	05/01	09/30	189	124	313	06/01/2019
ALASKA	HOMER	10/01	04/30	129	124	253	06/01/2019
ALASKA	JB ELMENDORF-RICHARDSON	05/01	08/31	229	125	354	06/01/2019
ALASKA	JB ELMENDORF-RICHARDSON	09/01	04/30	199	125	324	06/01/2019
ALASKA	JUNEAU	04/16	09/15	189	118	307	06/01/2019
ALASKA	JUNEAU	09/16	04/15	169	118	287	06/01/2019
ALASKA	KAKTOVIK	01/01	12/31	161	129	*290	06/01/2019
ALASKA	KAVIK CAMP	01/01	12/31	161	113	*274	06/01/2019
ALASKA	KENAI-SOLDOTNA	05/01	09/30	159	113	272	06/01/2019
ALASKA	KENAI-SOLDOTNA	10/01	04/30	89	113	202	06/01/2019
ALASKA	KENNICOTT	01/01	12/31	161	85	246	06/01/2019
ALASKA	KETCHIKAN	04/01	10/01	250	118	368	06/01/2019
ALASKA	KETCHIKAN	10/02	03/31	160	118	278	06/01/2019
ALASKA	KING SALMON	01/01	12/31	161	89	250	06/01/2019
ALASKA	KING SALMON LRRS	01/01	12/31	161	113	274	06/01/2019
ALASKA	KLAWOCK	05/01	09/30	139	94	233	06/01/2019
ALASKA	KLAWOCK	10/01	04/30	109	94	203	06/01/2019
ALASKA	KODIAK	05/01	09/30	194	109	303	06/01/2019
ALASKA	KODIAK	10/01	04/30	136	109	245	06/01/2019
ALASKA	KOTZEBUE	01/01	12/31	161	121	282	06/01/2019
ALASKA	KULIS AGS	05/01	08/31	229	125	354	06/01/2019
ALASKA	KULIS AGS	09/01	04/30	199	125	324	06/01/2019
ALASKA	MCCARTHY	01/01	12/31	161	85	246	06/01/2019
ALASKA	MCGRATH	01/01	12/31	161	113	*274	06/01/2019
ALASKA	MURPHY DOME	05/16	09/15	154	100	254	06/01/2019
ALASKA	MURPHY DOME	09/16	05/15	75	100	175	06/01/2019
ALASKA	NOME	01/01	12/31	185	118	303	06/01/2019
ALASKA	NOSC ANCHORAGE	05/01	08/31	229	125	354	06/01/2019
ALASKA	NOSC ANCHORAGE	09/01	04/30	199	125	324	06/01/2019
ALASKA	NUIQSUT	01/01	12/31	161	113	*274	06/01/2019
ALASKA	OLIKTOK LRRS	01/01	12/31	161	113	274	06/01/2019
ALASKA	PALMER	01/01	12/31	155	117	272	06/01/2019
ALASKA	PETERSBURG	01/01	12/31	130	108	238	06/01/2019
ALASKA	POINT BARROW LRRS	01/01	12/31	161	113	274	06/01/2019
ALASKA	POINT HOPE	01/01	12/31	161	113	*274	06/01/2019
ALASKA	POINT LONELY LRRS	01/01	12/31	161	113	274	06/01/2019
ALASKA	PORT ALEXANDER	01/01	12/31	161	113	*274	06/01/2019
ALASKA	PORT ALSWORTH	01/01	12/31	161	113	274	06/01/2019
ALASKA	PRUDHOE BAY	01/01	12/31	120	113	*233	06/01/2019
ALASKA	SELDOVIA	05/01	09/30	189	124	313	06/01/2019
ALASKA	SELDOVIA	10/01	04/30	129	124	253	06/01/2019
ALASKA	SEWARD	04/02	09/30	309	146	455	06/01/2019
ALASKA	SEWARD	10/01	04/01	80	146	226	06/01/2019
ALASKA	SITKA-MT. EDGECUMBE	04/01	09/30	245	116	361	06/01/2019

State or territory	Locality	Season start	Season end	Lodging	M&IE	Total per diem	Effective date
ALASKA	SITKA-MT. EDGECUMBE	10/01	03/31	200	116	316	06/01/2019
ALASKA	SKAGWAY	04/01	10/01	250	118	368	06/01/2019
ALASKA	SKAGWAY	10/02	03/31	160	118	278	06/01/2019
ALASKA	SLANA	01/01	12/31	161	113	274	06/01/2019
ALASKA	SPARREVOHN LRRS	01/01	12/31	161	113	274	06/01/2019
ALASKA	SPRUCE CAPE	05/01	09/30	194	109	303	06/01/2019
ALASKA	SPRUCE CAPE	10/01	04/30	136	109	245	06/01/2019
ALASKA	ST. GEORGE	01/01	12/31	161	113	274	06/01/2019
ALASKA	TALKEETNA	01/01	12/31	161	120	281	06/01/2019
ALASKA	TANANA	01/01	12/31	185	118	303	06/01/2019
ALASKA	TATALINA LRRS	01/01	12/31	161	113	274	06/01/2019
ALASKA	TIN CITY LRRS	01/01	12/31	161	113	274	06/01/2019
ALASKA	TOK	04/01	09/30	105	113	218	06/01/2019
ALASKA	TOK	10/01	03/31	99	113	212	06/01/2019
ALASKA	VALDEZ	05/16	09/15	197	110	307	06/01/2019
ALASKA	VALDEZ	09/16	05/15	179	110	289	06/01/2019
ALASKA	WAINWRIGHT	01/01	12/31	275	77	352	06/01/2019
ALASKA	WAKE ISLAND DIVERT AIRFIELD	01/01	12/31	161	113	274	06/01/2019
ALASKA	WASILLA	05/01	09/29	162	94	256	06/01/2019
ALASKA	WASILLA	09/30	04/30	98	94	192	06/01/2019
ALASKA	WRANGELL	04/01	10/01	250	118	368	06/01/2019
ALASKA	WRANGELL	10/02	03/31	160	118	278	06/01/2019
ALASKA	YAKUTAT	01/01	12/31	150	111	261	06/01/2019
AMERICAN SAMOA	AMERICAN SAMOA	01/01	12/31	139	86	225	07/01/2019
AMERICAN SAMOA	PAGO PAGO	01/01	12/31	139	86	225	07/01/2019
GUAM	GUAM (INCL ALL MIL INSTAL)	01/01	12/31	159	96	255	09/01/2019
GUAM	JOINT REGION MARIANAS (ANDERSEN).	01/01	12/31	159	96	255	09/01/2019
GUAM	JOINT REGION MARIANAS (NAVAL BASE).	01/01	12/31	159	96	255	09/01/2019
GUAM	TAMUNING	01/01	12/31	159	96	255	09/01/2019
HAWAII	[OTHER]	01/01	12/31	218	149	367	07/01/2019
HAWAII	CAMP H M SMITH	01/01	12/31	177	149	326	07/01/2019
HAWAII	EASTPAC NAVAL COMP TELE AREA.	01/01	12/31	177	149	326	07/01/2019
HAWAII	FT. DERUSSEY	01/01	12/31	177	149	326	07/01/2019
HAWAII	FT. SHAFTER	01/01	12/31	177	149	326	07/01/2019
HAWAII	HICKAM AFB	01/01	12/31	177	149	326	07/01/2019
HAWAII	HILO	01/01	12/31	199	120	319	07/01/2019
HAWAII	HONOLULU	01/01	12/31	177	149	326	07/01/2019
HAWAII	ISLE OF HAWAII: HILO	01/01	12/31	199	120	319	07/01/2019
HAWAII	ISLE OF HAWAII: OTHER	01/01	12/31	218	156	374	07/01/2019
HAWAII	ISLE OF KAUAI	01/01	12/31	325	141	466	07/01/2019
HAWAII	ISLE OF MAUI	01/01	12/31	304	150	454	07/01/2019
HAWAII	ISLE OF OAHU	01/01	12/31	177	149	326	07/01/2019
HAWAII	JB PEARL HARBOR-HICKAM	01/01	12/31	177	149	326	07/01/2019
HAWAII	KAPOLEI	01/01	12/31	177	149	326	07/01/2019
HAWAII	KEKAHA PACIFIC MISSILE RANGE FAC.	01/01	12/31	325	141	466	07/01/2019
HAWAII	KILAUEA MILITARY CAMP	01/01	12/31	199	120	319	07/01/2019
HAWAII	LANAI	01/01	12/31	218	134	352	07/01/2019
HAWAII	LIHUE	01/01	12/31	325	141	466	07/01/2019
HAWAII	LUALUALEI NAVAL MAGAZINE	01/01	12/31	177	149	326	07/01/2019
HAWAII	MCB HAWAII	01/01	12/31	177	149	326	07/01/2019
HAWAII	MOLOKAI	01/01	12/31	218	106	324	07/01/2019
HAWAII	NOSC PEARL HARBOR	01/01	12/31	177	149	326	07/01/2019
HAWAII	PEARL HARBOR	01/01	12/31	177	149	326	07/01/2019
HAWAII	PMRF BARKING SANDS	01/01	12/31	325	141	466	07/01/2019
HAWAII	SCHOFIELD BARRACKS	01/01	12/31	177	149	326	07/01/2019
HAWAII	TRIPLER ARMY MEDICAL CENTER.	01/01	12/31	177	149	326	07/01/2019
HAWAII	WAHIAWA NCTAMS PAC	01/01	12/31	177	149	326	07/01/2019
HAWAII	WHEELER ARMY AIRFIELD	01/01	12/31	177	149	326	07/01/2019
MIDWAY ISLANDS	MIDWAY ISLANDS	01/01	12/31	125	81	206	07/01/2019
NORTHERN MARIANA ISLANDS	[OTHER]	01/01	12/31	69	113	182	09/01/2019
NORTHERN MARIANA ISLANDS	ROTA	01/01	12/31	130	114	244	09/01/2019
NORTHERN MARIANA ISLANDS	SAIPAN	01/01	12/31	161	113	274	09/01/2019
NORTHERN MARIANA ISLANDS	TINIAN	01/01	12/31	69	93	162	09/01/2019
PUERTO RICO	[OTHER]	01/01	12/31	154	100	254	06/01/2020
PUERTO RICO	AGUADILLA	01/01	12/31	149	90	239	06/01/2020
PUERTO RICO	BAYAMON	12/01	05/31	195	115	310	06/01/2020
PUERTO RICO	BAYAMON	06/01	11/30	167	115	282	06/01/2020
PUERTO RICO	CAROLINA	12/01	05/31	195	115	310	06/01/2020
PUERTO RICO	CAROLINA	06/01	11/30	167	115	282	06/01/2020
PUERTO RICO	CEIBA	01/01	12/31	159	110	269	06/01/2020
PUERTO RICO	CULEBRA	01/01	12/31	159	105	264	06/01/2020
PUERTO RICO	FAJARDO [INCL ROOSEVELT RDS NAVSTAT].	01/01	12/31	159	110	269	06/01/2020
PUERTO RICO	FT. BUCHANAN [INCL GSA SVC CTR, GUAYNABO].	12/01	05/31	195	115	310	06/01/2020
PUERTO RICO	FT. BUCHANAN [INCL GSA SVC CTR, GUAYNABO].	06/01	11/30	167	115	282	06/01/2020
PUERTO RICO	HUMACAO	01/01	12/31	159	110	269	06/01/2020

State or territory	Locality	Season start	Season end	Lodging	M&IE	Total per diem	Effective date
PUERTO RICO	LUIS MUNOZ MARIN IAP AGS	12/01	05/31	195	115	310	06/01/2020
PUERTO RICO	LUIS MUNOZ MARIN IAP AGS	06/01	11/30	167	115	282	06/01/2020
PUERTO RICO	LUQUILLO	01/01	12/31	159	110	269	06/01/2020
PUERTO RICO	MAYAGUEZ	01/01	12/31	109	94	203	06/01/2020
PUERTO RICO	PONCE	01/01	12/31	149	130	279	06/01/2020
PUERTO RICO	RIO GRANDE	01/01	12/31	154	85	239	06/01/2020
PUERTO RICO	SABANA SECA [INCL ALL MILITARY].	12/01	05/31	195	115	310	06/01/2020
PUERTO RICO	SABANA SECA [INCL ALL MILITARY].	06/01	11/30	167	115	282	06/01/2020
PUERTO RICO	SAN JUAN & NAV RES STA	12/01	05/31	195	115	310	06/01/2020
PUERTO RICO	SAN JUAN & NAV RES STA	06/01	11/30	167	115	282	06/01/2020
PUERTO RICO	VIEQUES	01/01	12/31	159	94	253	06/01/2020
VIRGIN ISLANDS (U.S.)	ST. CROIX	12/15	04/14	299	120	419	04/01/2020
VIRGIN ISLANDS (U.S.)	ST. CROIX	04/15	12/14	247	120	367	04/01/2020
VIRGIN ISLANDS (U.S.)	ST. JOHN	12/04	04/30	230	123	353	04/01/2020
VIRGIN ISLANDS (U.S.)	ST. JOHN	05/01	12/03	170	123	293	04/01/2020
VIRGIN ISLANDS (U.S.)	ST. THOMAS	04/15	12/15	249	118	367	04/01/2020
VIRGIN ISLANDS (U.S.)	ST. THOMAS	12/16	04/14	339	118	457	04/01/2020
WAKE ISLAND	WAKE ISLAND	01/01	12/31	129	70	199	09/01/2019

*Where meals are included in the lodging rate, a traveler is only allowed a meal rate on the first and last day of travel.

[FR Doc. 2020–11604 Filed 5–28–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DOD–2020–OS–0055]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Deputy Assistant Secretary of Defense for Military Community and Family Policy, announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by July 28, 2020.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Military Community and Family Policy, Office of Military Family Readiness, ATTN: Karen Morgan, Alexandria, VA 22350; *karen.s.morgan4.civ@mail.mil* or by telephone: (571) 372–0859 or FAX: (571) 372–0884.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Department of Defense Consent to Conduct Installation Records Checks (IRC) DD Form 3058; OMB Control Number 0704–0586.

Needs And Uses: The information collection requirement is necessary as part of a criminal history background investigation on individual working, volunteering or residing on a military installation who provides care and services to children in DoD programs. The query of records from the installation includes: the Family Advocacy Central Registry, the military law enforcement records and the Defense Central Index of Investigations (DCII). The query of records will assist the department in obtaining or maintaining an employment suitability or fitness determination for those individuals working with children on military installations. Programs impacted are referenced within the 34 U.S. Code § 20351 (Crime Control Act of 1990) and include impacted individuals such as employees, DoD contractors, providers, adults residing in a family child care home, volunteers, and others with regular recurring contact with children.

Affected Public: Individuals and Households.

Annual Burden Hours: 2,333.

Number of Respondents: 14,000.

Responses per Respondent: 1.

Annual Responses: 14,000.

Average Burden per Response: 10 minutes.

Frequency: Upon initial employment/participation; every five years (upon reverification or the latest guidance from DoD); and/or annually for FCC providers.

Respondents are DoD contractors, family child care providers, family child care adult family members residing in the home, and specified volunteers who provide child care services for children. This form will be initiated by DoD staff and will be maintained in the initiating DoD offices and/or appropriate human resources or security offices.

Dated: May 26, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–11553 Filed 5–28–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2020–OS–0051]

Proposed Collection; Comment Request

AGENCY: Defense Finance and Accounting Service, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Finance and Accounting Service announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by July 28, 2020.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write Defense Finance and Accounting Service ATTN: DFAS–IN/ZPFA, 8899 East 56th St., Indianapolis, IN 46249–0500, Denise Shaffer, (317) 212–4461.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Statement of Claimant Requesting Recertified Check; DD Form 2660; OMB Number 0730–0002.

Needs and Uses: The information collection requirement is necessary to be in accordance with TFM Volume 1, Part 4, Section 7060.20 and DoD 7000.14–R, Volume 5, where there is a requirement that a payee identify himself/herself and certify as to what happened to the original check issued by the government (non-receipt, loss, destruction, theft, etc.). This collection will be used to identify rightful reissuance of government checks to individuals or businesses outside the Department of Defense.

Affected Public: Individuals or Households.

Annual Burden Hours: 3,180.

Number of Respondents: 38,157.

Responses per Respondent: 1.

Annual Responses: 38,157.

Average Burden per Response: 5 minutes.

Frequency: On occasion.

The Statement of Claimant Requesting Recertified Check is used to ascertain pertinent information needed by the Department of Defense in order to reissue checks to payees, if the checks have not been negotiated to financial institutions within one (1) year of the date of issuance, when an original check has been lost, not received, damaged, stolen, etc. The form will be completed by the payee who was issued the original check. The information provided on this form will be used in determining whether a check may be reissued to the named payee.

Dated: May 26, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–11607 Filed 5–28–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2020–OS–0052]

Proposed Collection; Comment Request

AGENCY: Defense Finance and Accounting Service, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Defense Finance and Accounting Service announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by July 28, 2020.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Defense Finance and Accounting Service ATTN: DFAS–IN/ZPFA, 8899 East 56th St., Indianapolis, IN 46249–0500, Denise Shaffer, (317) 212–4461.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Personal Check Cashing Agreement, DD Form 2761, OMB Control Number 0730–0005.

Needs and Uses: The information collection requirement is necessary to meet the Department of Defense's (DoD) requirement for cashing personal checks overseas and afloat by DoD disbursing activities, as provided in 31 U.S.C. 3342. The DoD Financial Management Regulation, Volume 5, provides guidance to DoD disbursing officers in the performance of this information collection. This allows the DoD disbursing officer or authorized agent

the authority to offset the pay without prior notification in cases where this form has been signed subject to conditions specified within the approved procedures.

Affected Public: Individuals or households.

Annual Burden Hours: 1187.

Number of Respondents: 4748.

Responses per Respondent: 1.

Annual Responses: 4748.

Average Burden per Response: 15 minutes.

Frequency: On occasion.

The Personal Check Cashing Agreement form is designed exclusively to help the DoD disbursing offices expedite the collection process of dishonored checks. The front of the form will be completed and signed by the authorized individual requesting check cashing privileges. By signing the form, the individual is freely and voluntarily consenting to the immediate collection from their current pay, without prior notice, for the face value of any check cashed, plus any charges assessed against the government by a financial institution, in the event the check is dishonored. In the event the check is dishonored, the disbursing office will complete and certify the reverse side of the form and forward the form to the applicable payroll office for collection from the individual's current pay.

Dated: May 26, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–11605 Filed 5–28–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Department of Defense Military Family Readiness Council; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal Advisory Committee meeting of the DoD Military Family Readiness Council (MFRC) will take place.

DATES: Open to the public Tuesday, June 9, 2020, from 10:00 a.m. to 12:00 p.m.

ADDRESSES: The address of this open meeting will be online. The phone number for the remote access is 800–309–1256, and the participant code is 838869. This information will also be posted on the DoD MFRC website at: *http://www.militaryonesource.mil/those-who-support-mfrc*.

FOR FURTHER INFORMATION CONTACT: William Story, (571) 372–5345 (Voice), (571) 372–0884 (Facsimile), OSD Pentagon OUSD P–R Mailbox Family Readiness Council, *osd.pentagon.ousd-p-r.mbx.family-readiness-council@mail.mil* (Email). Mailing address is Office of the Deputy Assistant Secretary of Defense for Military Community and Family Policy, Office of Family Readiness Policy, 4800 Mark Center Drive, Alexandria, VA 22350–2300, Room 3G15. Website: *http://www.militaryonesource.mil/those-who-support-mfrc*. The most up-to-date changes to the meeting agenda can be found on the website.

SUPPLEMENTARY INFORMATION: Due to circumstances beyond the control of the DoD and the Designated Federal Officer (DFO), the DoD MFRC was unable to provide public notification required by 41 CFR 102–3.150(a) concerning the meeting for June 9, 2020. Accordingly, the Advisory Committee Management Officer for the DoD, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

This meeting is being held under the provisions of the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.140 and 102–3.150.

Purpose of the Meeting: This is the second meeting of the Council for Fiscal Year (FY) 2020. During this meeting the MFRC Members will hear presentations addressing the second focus area for FY 2020, Community Collaboratives and Partnerships.

Agenda: Call to Order, Welcome & Opening Remarks; Administrative Issues; Written Public Submissions; Community Collaboratives and Partnerships Presentations; Building Healthy Military Communities Pilot; DoD Collaboration and Partnerships with State Governments; Military OneSource—Connecting Our Military Community; Questions and Answers Session and Council Member Discussion; Closing Remarks. Note: Exact order may vary.

Meeting Accessibility: Members of the public who are interested in hearing the MFRC meeting may call in using the remote access number 800–309–1256 and participant code 838869.

Written Statements: Persons interested in providing a written statement for review and consideration by Council members attending the June 9 meeting must do so no later than close of business Tuesday, June 2, 2020, through the Council mailbox (*osd.pentagon.ousd-p-r.mbx.family-readiness-council@mail.mil*). Written statements received after this date will be provided to Council members in preparation for the next MFRC meeting. The DFO will review all submitted written statements and provide copies to all MFRC members. Written statements should not include personally identifiable information such as names of adults and children, phone numbers, addresses, social security numbers, and other contact information within the body of the written statement.

Dated: May 26, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–11609 Filed 5–28–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DOD–2020–OS–0053]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Under Secretary of Defense for Personnel and Readiness announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by July 28, 2020.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Ms. Angela James, Office of Information Management, DoD, at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil* or call 571–372–7574.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Application for Review by the Physical Disability Board of Review; DD Form 294; OMB Control Number 0704–0453.

Needs and Uses: The Fiscal Year 2008 National Defense Authorization Act amended Title 10, United States Code by adding Section 1554a. That provision of law directs the Secretary of Defense to establish a board of review to review the disability determinations of individuals who were separated from the armed forces during the period beginning on September 11, 2001 and ending on December 31, 2009 due to unfitness for duty due to a medical condition with a disability rating of 20 percent disabled or less; and were found to be not eligible for retirement. On June 27, 2008, The Department of Defense published DODI 6040.44, which provides the guidance for this process.

The DD Form 294, ''Application for Review by the Physical Disability Board of Review (PDBR) of the Rating Awarded Accompanying a Medical Separation from the Armed Forces of the United States'' is designed to appropriately collect the information necessary to retrieve the medical separation and the Department of Veterans Affairs records and correct military personnel and pay records.

Affected Public: Individuals and Household.

Annual Burden Hours: 180.

Number of Respondents: 240.

Responses per Respondent: 1.

Annual Responses: 240.

Average Burden per Response: 45 minutes.

Frequency: On occasion.

Dated: May 26, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–11545 Filed 5–28–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

[Docket ID USN–2019–HQ–0021]

Submission for OMB Review; Comment Request

AGENCY: The Office of the Secretary of the Navy, Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by June 29, 2020.

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.

FOR FURTHER INFORMATION CONTACT: Angela James, 571–372–7574, or *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil*.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Marine Corps Marathon Race Applications; OMB Control Number 0703–0053.

Type of Request: Revision.

Number of Respondents: 60,200.

Responses per Respondent: 1.

Annual Responses: 60,200.

Average Burden per Response: 5 minutes.

Annual Burden Hours: 5,016.68.

Needs and Uses: The information collection requirement is necessary to obtain and record the information of runners to conduct the races, for timing purposes and for statistical use.

Affected Public: Individuals or households.

Frequency: Annually.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Jasmeet Seehra.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela James.

Requests for copies of the information collection proposal should be sent to Ms. James at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil*.

Dated: May 22, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–11534 Filed 5–28–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF ENERGY

[OE Docket No. EA–482]

Application To Export Electric Energy; DMG Blockchain Solutions Inc.

AGENCY: Office of Electricity, Department of Energy.

ACTION: Notice of application.

SUMMARY: DMG Blockchain Solutions Inc. (Applicant or DMG) has applied for authorization to transmit electric energy from the United States to Canada pursuant to the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before June 29, 2020.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed by electronic mail to *Electricity.Exports@hq.doe.gov,* or by facsimile to (202) 586–8008.

SUPPLEMENTARY INFORMATION: The Department of Energy (DOE) regulates exports of electricity from the United States to a foreign country, pursuant to sections 301(b) and 402(f) of the Department of Energy Organization Act (42 U.S.C. 7151(b) and 42 U.S.C.

7172(f)). Such exports require authorization under section 202(e) of the Federal Power Act (16 U.S.C. 824a(e)).

On May 21, 2020, DMG filed an application with DOE (Application or App.) to transmit electric energy from the United States to Canada for a term of five years. DMG states that it ''is a British Columbia corporation with its office and principal place of business in Vancouver, British Columbia, Canada'' and that it ''has a US subsidiary in Sunnyvale, California.'' App. at 1. DMG adds that it ''does not own, operate or control any electric generation assets, not is it affiliates with any entity that owns generation assets in the United States,'' and that ''[n]either DMG nor any of its affiliates holds a franchise or service territory for the transmission, distribution or sale of electric power.'' *Id.* at 2.

DMG further states that it ''will purchase power to be exported from electric utilities, federal power marketing agencies, qualifying cogeneration, small power production facilities and exempt wholesale generators as those terms defined in the FPA.'' App. at 3. DMG contends that its proposed exports will not impair the sufficiency of electric supply within the United States and will neither impede nor tend to impede the operational reliability of the bulk power system. *See id.*

The existing international transmission facilities to be utilized by the Applicant have previously been authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the Application at the address provided above. Protests should be filed in accordance with Rule 211 of the Federal Energy Regulatory Commission's (FERC) Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to become a party to this proceeding should file a motion to intervene at the above address in accordance with FERC Rule 214 (18 CFR 385.214).

Comments and other filings concerning DMG's application to export electric energy to Canada should be clearly marked with OE Docket No. EA–482. Additional copies are to be provided directly to Sheldon Bennet, 1090 Homer Street, Suite 490, Vancouver, British Columbia, V6B 2W9, Canada; *sheldon@dmgblockchain.com.*

A final decision will be made on this Application after the environmental impacts have been evaluated pursuant to DOE's National Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after DOE determines that the proposed action will not have an adverse impact on the sufficiency of supply or reliability of the U.S. electric power supply system.

Copies of this Application will be made available, upon request, by accessing the program website at *http://energy.gov/node/11845,* or by emailing Matthew Aronoff at *matthew.aronoff@hq.doe.gov*.

Signed in Washington, DC, on May 26, 2020.

Christopher Lawrence,

Management and Program Analyst, Transmission Permitting and Technical Assistance, Office of Electricity.

[FR Doc. 2020–11601 Filed 5–28–20; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL20–48–000]

PP&L Industrial Customer Alliance v. PPL Electric Utilities Corporation; Notice of Complaint

Take notice that on May 21, 2020, pursuant to sections 206, 306 and 309 of the Federal Power Act, and Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206 (2019), PP&L Industrial Customer Alliance, (Complainant) filed a formal complaint alleging that the current 11.18% base return on equity of PPL Electric Utilities Corporation is excessive and should be reduced as of the date of the complaint, as more fully explained in the complaint.

Complainant certifies that copies of the complaint were served on the contacts as listed on the Commission's list of Corporate Officials.

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. All interventions, or protests must be filed on or before the comment date.

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.

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://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.

Comment Date: 5:00 Eastern Time on June 10, 2020.

Dated: May 22, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–11557 Filed 5–28–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG20–169–000.

Applicants: Helios 5 MT, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Helios 5 MT, LLC.

Filed Date: 5/22/20.

Accession Number: 20200522–5108.

Comments Due: 5 p.m. ET 6/12/20.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER15–1436–001.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.19a(b): Refund Report Entergy Operating Companies to be effective N/A.

Filed Date: 5/22/20.

Accession Number: 20200522–5143.

Comments Due: 5 p.m. ET 6/12/20.

Docket Numbers: ER17–1742–002; ER19–2671–001; ER19–2672–001; ER19–2595–001; ER19–2670–001; ER17–311–002; ER13–2490–006.

Applicants: Hattiesburg Farm, LLC, SR Arlington II, LLC, SR Arlington II MT, LLC, SR Hazlehurst III, LLC, SR Meridian III, LLC, SR South Loving LLC, Simon Solar Farm LLC.

Description: Notice of Non-Material Change in Status of Hattiesburg Farm, LLC, et. al.

Filed Date: 5/21/20.

Accession Number: 20200521–5211.

Comments Due: 5 p.m. ET 6/11/20.

Docket Numbers: ER20–1059–001.

Applicants: Southwest Power Pool, Inc.

Description: Tariff Amendment: Deficiency Response—Western Energy Imbalance Service Tariff to be effective 2/1/2021.

Filed Date: 5/22/20.

Accession Number: 20200522–5187.

Comments Due: 5 p.m. ET 6/12/20.

Docket Numbers: ER20–1060–001.

Applicants: Southwest Power Pool, Inc.

Description: Tariff Amendment: Deficiency Response—Western Energy Imbalance Service Rate Schedule Tariff to be effective 2/1/2021.

Filed Date: 5/22/20.

Accession Number: 20200522–5191.

Comments Due: 5 p.m. ET 6/12/20.

Docket Numbers: ER20–1876–001.

Applicants: Evergy Kansas Central, Inc.

Description: Tariff Amendment: Notice of Succession of Rate Schedule, Supplemental to be effective 7/20/2020.

Filed Date: 5/21/20.

Accession Number: 20200521–5146.

Comments Due: 5 p.m. ET 6/11/20.

Docket Numbers: ER20–1877–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: First Rev. ISA SA No. 3601 & Original ICSA SA No. 5630; Queue No. V3–028/AB2–170 to be effective 4/22/2020.

Filed Date: 5/21/20.

Accession Number: 20200521–5135.

Comments Due: 5 p.m. ET 6/11/20.

Docket Numbers: ER20–1878–000.

Applicants: Evergy Kansas South, Inc.

Description: § 205(d) Rate Filing: Notice of Succession Rate Schedules & Service Agreements to be effective 7/20/2020.

Filed Date: 5/21/20.

Accession Number: 20200521–5139.

Comments Due: 5 p.m. ET 6/11/20.

Docket Numbers: ER20–1879–000.

Applicants: Oliver Wind I, LLC.

Description: Baseline eTariff Filing: Oliver Wind I, LLC Application for MBR Authorization to be effective 7/21/2020.

Filed Date: 5/21/20.

Accession Number: 20200521–5162.

Comments Due: 5 p.m. ET 6/11/20.

Docket Numbers: ER20–1880–000.

Applicants: Evergy Metro, Inc.

Description: § 205(d) Rate Filing: Notice of Succession Rate Schedules & Service Agreements to be effective 7/20/2020.

Filed Date: 5/21/20.

Accession Number: 20200521–5169.

Comments Due: 5 p.m. ET 6/11/20.

Docket Numbers: ER20–1881–000.

Applicants: Tampa Electric Company.

Description: § 205(d) Rate Filing: Emergency Interchange Service Schedule A&B–2020 (Bundled) to be effective 5/1/2020.

Filed Date: 5/22/20.

Accession Number: 20200522–5000.

Comments Due: 5 p.m. ET 6/12/20.

Docket Numbers: ER20–1882–000.

Applicants: Evergy Missouri West, Inc.

Description: § 205(d) Rate Filing: Notice of Succession Rate Schedules & Service Agreements to be effective 7/21/2020.

Filed Date: 5/22/20.

Accession Number: 20200522–5001.

Comments Due: 5 p.m. ET 6/12/20.

Docket Numbers: ER20–1883–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Revisions to Sch. 12–Appx A: April 2020 RTEP, 30-Day Comment Period Requested to be effective 8/20/2020.

Filed Date: 5/22/20.

Accession Number: 20200522–5058.

Comments Due: 5 p.m. ET 6/12/20.

Docket Numbers: ER20–1884–000.

Applicants: Invenergy Wilkinson Solar Holdings LLC.

Description: Tariff Cancellation: Notice of Cancellation of Market-Based Rate Tariff to be effective 7/22/2020.

Filed Date: 5/22/20.

Accession Number: 20200522–5128.

Comments Due: 5 p.m. ET 6/12/20.

Docket Numbers: ER20–1885–000.

Applicants: Polaris Wind Energy LLC.

Description: Tariff Cancellation: Notice of Cancellation of Market-Based Rate Tariff to be effective 7/22/2020.

Filed Date: 5/22/20.

Accession Number: 20200522–5147.

Comments Due: 5 p.m. ET 6/12/20.

Docket Numbers: ER20–1886–000.

Applicants: Appalachian Power Company, Indiana Michigan Power Company, Kentucky Power Company, Kingsport Power Company, Ohio Power Company, Wheeling Power Company, American Electric Power Service Corporation, PJM Interconnection, L.L.C.

Description: Compliance filing: AEP East Operating Companies submits revisions to OATT Att. H–14 re: Order 864 to be effective 1/27/2020.

Filed Date: 5/22/20.

Accession Number: 20200522–5183.

Comments Due: 5 p.m. ET 6/12/20.

Docket Numbers: ER20–1887–000.

Applicants: GenOn Chalk Point, LLC.

Description: § 205(d) Rate Filing: Notice of Succession to be effective 4/22/2020.

Filed Date: 5/22/20.

Accession Number: 20200522–5186.

Comments Due: 5 p.m. ET 6/12/20.

Docket Numbers: ER20–1888–000.

Applicants: AEP Appalachian Transmission Company, Inc, AEP Indiana Michigan Transmission Company, Inc., AEP Kentucky Transmission Company, Inc., AEP Ohio Transmission Company, Inc., AEP West Virginia Transmission Company, Inc., American Electric Power Service Corporation, PJM Interconnection, L.L.C.

Description: Compliance filing: AEP East Transmission Companies submit revisions to OATT Att. H–20 re: Order 864 to be effective 1/27/2020.

Filed Date: 5/22/20.

Accession Number: 20200522–5229.

Comments Due: 5 p.m. ET 6/12/20.

Docket Numbers: ER20–1889–000.

Applicants: Public Service Electric and Gas Company, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: PSEG submits Revisions to PJM Tariff, Att. H–10 re: Order 864 to be effective 1/27/2020.

Filed Date: 5/22/20.

Accession Number: 20200522–5244.

Comments Due: 5 p.m. ET 6/12/20.

Docket Numbers: ER20–1890–000.

Applicants: California Independent System Operator Corporation.

Description: § 205(d) Rate Filing: 2020–05–22 Intertie Deviation Settlement—Initial Filing to be effective 10/1/2020.

Filed Date: 5/22/20.

Accession Number: 20200522–5246.

Comments Due: 5 p.m. ET 6/12/20.

Docket Numbers: ER20–1891–000.

Applicants: Oliver Wind II, LLC.

Description: § 205(d) Rate Filing: Oliver Wind II, LLC Notice of Succession to be effective 5/23/2020.

Filed Date: 5/22/20.

Accession Number: 20200522–5247.
Comments Due: 5 p.m. ET 6/12/20.
Docket Numbers: ER20–1892–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Limited waiver request of Midcontinent Independent System Operator, Inc.
Filed Date: 5/22/20.
Accession Number: 20200522–5290.
Comments Due: 5 p.m. ET 6/12/20.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf*. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: May 22, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–11556 Filed 5–28–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP20–53–000]

National Fuel Gas Supply Corporation; Notice of Schedule for Environmental Review of the Amendment to West Side Expansion and Modernization Project

On February 18, 2020, National Fuel Gas Supply Corporation (National Fuel) filed an application pursuant to section 7(c) of the Natural Gas Act to amend the certificate of public convenience and necessity issued by the Commission on March 2, 2015 in Docket No. CP14–70–000 authorizing the West Side Expansion and Modernization Project (Project). The proposed amendment seeks to remove the ''spare'' designation from compression at its Mercer Compressor Station in Mercer County, Pennsylvania.

On February 27, 2020, the Federal Energy Regulatory Commission (Commission or FERC) issued its Notice of Application for Amendment. Among other things, that notice alerted agencies issuing federal authorizations of the requirement to complete all necessary reviews and to reach a final decision on a request for a federal authorization within 90 days of the date of issuance of the Commission staff's Environmental Assessment (EA) for the Project amendment. This instant notice identifies the FERC staff's planned schedule for the completion of the EA for the Project amendment.

Schedule for Environmental Review

Issuance of EA—June 19, 2020
90-day Federal Authorization Decision Deadline—September 17, 2020

If a schedule change becomes necessary, additional notice will be provided so that the relevant agencies are kept informed of the Project amendment's progress.

Project Description

In Docket No. CP14–70–000, National Fuel received authorization to designate 1,775 horsepower (HP) of compression out of 7,100 HP at the Mercer Compressor Station as ''spare'' compression. National Fuel is now seeking in the Project amendment authorization to remove the ''spare'' designation from the 1,775 HP of compression at its Mercer Compressor Station to accommodate a subscribing shipper's request to direct a portion of its firm transportation capacity to a different primary delivery point.

Background

On March 26, 2020, the Commission issued a *Notice of Intent to Prepare an Environmental Assessment for the Proposed Amendment to West Side Expansion and Modernization Project and Request for Comments on Environmental Issues* (NOI). In response to the NOI, the Commission received no environmental comments. The Commission did receive comments regarding rates and tariffs.

Additional Information

Additional information about the Project is available from the Commission's Office of External Affairs at (866) 208–FERC or on the FERC website (*www.ferc.gov*). Using the ''eLibrary'' link, select ''General Search'' from the eLibrary menu, enter the selected date range and ''Docket Number'' excluding the last three digits (*i.e.,* CP20–53), and follow the instructions. For assistance with access to eLibrary, the helpline can be reached at (866) 208–3676, TTY (202) 502–8659, or at *FERCOnlineSupport@ferc.gov*. The eLibrary link on the FERC website also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rule makings.

Dated: May 22, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–11588 Filed 5–28–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2894–013]

Flambeau Hydro, LLC; Notice of Availability of Environmental Assessment

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission or FERC) regulations, 18 CFR part 380 (Order No. 486, 52 **Federal Register** 47897), the Office of Energy Projects has reviewed the application for a subsequent license for the Black Brook Hydroelectric Project (FERC Project No. 2894–013), located on the Apple River in Polk County, Wisconsin. The project does not occupy federal land.

The environmental assessment (EA) analyzes the potential environmental effects of continuing to operate the project, and concludes that issuing a subsequent license for the project, with appropriate environmental measures, would not constitute a major federal action significantly affecting the quality of the human environment.

The Commission provides all interested persons an opportunity to view and/or print the EA 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 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 FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll-free at (866) 208–3676, or for TTY, (202) 502–8659. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other

pending projects. For assistance, contact FERC Online Support.

Any comments should be filed within 30 days from the date of this notice. The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp*. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp*. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support.

For further information, please contact Michael Davis by phone at (202) 502–8339, or by email at *michael.davis@ferc.gov*.

Dated: May 22, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–11581 Filed 5–28–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP20–881–000]

ETC Tiger Pipeline, LLC; Notice of Petition For Declaratory Order

Take notice that on May 19, 2020, pursuant to Rule 207(a)(2) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.207(a)(2) (2019), ETC Tiger Pipeline, LLC (Tiger) filed a petition for a declaratory order seeking a ruling to remove the uncertainty as to whether a counterparty to Tiger's transportation agreements must receive the Commission's approval under section 5 of the Natural Gas Act in order to reject such Commission-jurisdictional agreements in bankruptcy proceedings, all as more fully explained in the petition.

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. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

The Commission encourages electronic submission of 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.

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://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.

Comment Date: 5:00 p.m. Eastern time on June 18, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–11559 Filed 5–28–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC20–11–000]

Commission Information Collection Activities; Comment Request for Generic Clearance for the Collection of Qualitative Feedback on Commission Service Delivery

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995 (PRA), the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC–153, ''Generic Clearance for the Collection of Qualitative Feedback on Commission Service Delivery'' and submitting the information collection to the Office of Management and Budget (OMB) for review. Any interested person may file comments directly with OMB and should address a copy of those comments to the Commission as explained below.

DATES: Comments on the collection of information are due June 29, 2020.

ADDRESSES: Send written comments on FERC–153 to OMB through *www.reginfo.gov/public/do/PRAMain*. Attention: Federal Energy Regulatory Commission Desk Office. Please identify the OMB control number (1902–0293) in the subject line. Your comments should be sent within 30 days of publication of this notice in the **Federal Register**.

A copy of the comments should also be sent to the Commission (identified by Docket No. IC20–11–000) by either of the following methods:

- *eFiling at Commission's Website: http://www.ferc.gov/docs-filing/efiling.asp*.
- *Mail/Express Services:* 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.

Instructions

OMB submissions must be formatted and filed in accordance with submission guidelines at *www.reginfo.gov/public/do/PRAMain;* Using the search function under the ''Currently Under Review field,'' select Federal Energy Regulatory Commission; click ''submit'' and select ''comment'' to the right of the subject collection.

FERC submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov/help/submission-guide.asp*. For user assistance, contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov/docs-filing/docs-filing.asp*.

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* telephone at (202) 502–8663.

SUPPLEMENTARY INFORMATION:

Title: FERC–153, Generic Clearance for the Collection of Qualitative Feedback on Commission Service Delivery.

OMB Control No.: 1902–0293.

Type of Request: Generic information collection.

Abstract: On March 17, 2020, the Commission published a Notice in the **Federal Register** (85 FR 15159) in Docket No. IC20–11–000 requesting public comments. The Commission received no public comments and is indicating that in the related submittal to OMB. This information collection provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback, we mean data that provides useful insights on perceptions and opinions but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences, and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. This collection will allow for ongoing, collaborative and actionable communications between FERC and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

The solicitation of feedback will target areas such as: Timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Commission's services will be unavailable.

The Commission will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;
- The collections are low burden for respondents (based on considerations of total burden hours, total number of respondents, or burden hours per respondent) and are low-cost for both the respondents and the Federal Government;
- The collections are non-controversial and do not raise issues of concern to other Federal agencies;
- The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program soon;
- Personal identifiable information (PII) is collected only to the extent necessary and is not retained;
- Information gathered is intended to be used only internally for general service improvement and program management purposes and is not intended for release outside of the Commission (if released, the Commission must indicate the qualitative nature of the information);
- Information gathered will not be used for the purpose of substantially informing influential policy decisions; and
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study.

As a general matter, this information collection will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

This information collection is subject to the PRA. The Commission generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA 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 which does not display a valid OMB Control Number. See 5 CFR 1320.6(a). OMB authorization for an information collection cannot be for more than three years without renewal.

On March 17, 2020, the Commission published a Notice in the **Federal Register** in Docket No. IC20–11–000 requesting public comments. The Commission received no public comments.

Type of Respondents/Affected Public: Individuals and households; Businesses or other for-profit and not-for-profit organizations; State, Local, or Tribal government.

Estimate of Annual Burden: [1] The Commission estimates the annual public reporting burden and cost for the information collection as:

ESTIMATED ANNUAL BURDEN FOR GENERIC CLEARANCE FOR FERC–153

	Number of respondents	Number of responses per respondent	Total number of responses	Average burden minutes per response	Total burden hours
	(1)	(2)	(1) * (2) = (3)	(4)	(3) * (4) = (5)
Generic Clearance	27,000	1	27,000	10 minutes	4,500 hours.[2]

[1] Burden is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to 5 Code of Federal Regulations 1320.3.

Comments: Comments are invited on: (a) Whether the 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 estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: May 22, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–11583 Filed 5–28–20; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–10009–74–OMS]

Privacy Act of 1974; System of Records

AGENCY: Office of Mission Support, Environmental Protection Agency (EPA).

ACTION: Notice of a new system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, the Office of Mission Support (OMS) gives notice that it proposes to create a new system of records for the Personnel Security System (PSS) 2.0. OMS is replacing the current PSS (1.0), which is a module of the Office of Administrative Services Information System (OASIS, EPA–41), with a new stand-alone system, PSS 2.0, outside of the OASIS portal. All exemptions and provisions included in the SORN for PSS 1.0 under the OASIS portal will transfer to the new SORN for PSS 2.0.

DATES: Persons wishing to comment on this system of records notice must do so by June 29, 2020. New routine uses for this new system of records will be effective June 29, 2020.

ADDRESSES: Submit your comments, identified by Docket ID No. OMS–2019–0371, by one of the following methods:

Regulations.gov: www.regulations.gov. Follow the online instructions for submitting comments.

Email: oei.docket@epa.gov.

Fax: 202–566–1752.

Mail: OMS Docket, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

Hand Delivery: OMS Docket, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OMS–2019–0371. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Controlled Unclassified Information (CUI) or other information for which disclosure is restricted by statute. Do not submit information that you consider to be CUI or otherwise protected through *www.regulations.gov*. The *www.regulations.gov* website is an ''anonymous access'' system for EPA, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. Each agency determines submission requirements within their own internal processes and standards. EPA has no requirement of personal information. If you send an email comment directly to the EPA without going through *www.regulations.gov* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about the EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm*.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CUI or other information for which disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the OMS Docket, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC. 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 OMS Docket is (202) 566–1752.

FOR FURTHER INFORMATION CONTACT: Jon Ross, Office of Mission Support, Environmental Protection Agency, William Jefferson Clinton North Building, Mailcode 3206A, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number, (202) 564–6153; email address, *Ross.Jon@epa.gov*.

SUPPLEMENTARY INFORMATION: The Office of Mission Support (OMS) plans to replace the current PSS (1.0), which is a module of OASIS (EPA–41), with a new system, PSS 2.0, outside of the OASIS portal. OMS is creating a stand-alone Privacy Act system of records for the Personnel Security System (PSS) 2.0. All exemptions and provisions included in the SORN for PSS 1.0 under the OASIS portal will transfer to the new SORN for PSS 2.0. Details regarding the system of records are contained in this **Federal Register** Notice. The PSS 2.0 assists the Security Management Division (SMD) with tracking the documentation associated with security investigations for Federal and non-Federal personnel working for EPA. This includes reporting requirements that meet the Security Executive Agent Directive (SEAD) 3, which establishes reporting requirements for all ''covered individuals'' who have access to classified information or who hold a sensitive position. Access to the system is restricted to authorized users and will be maintained in a secure, password protected computer system, in secure areas and buildings with physical access controls and environmental controls. In the performance of their official duties, EPA federal personnel must input and manage Sensitive Personally Identifiable Information (such as SSN) and Personally Identifiable Information (such as home address and email address). The data is required in the system to start the onboarding process and to manage personnel through lifecycle activity at EPA (such as background investigations).

[2] 4,500 hours = 270,000 minutes.

SYSTEM NAME AND NUMBER:

Personnel Security System (PSS) 2.0—EPA–83.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

National Computer Center (NCC), 109 TW Alexander Drive, Research Triangle Park, Durham, NC 27711.

SYSTEM MANAGER (S):

Jon Ross, Security Management Division, Environmental Protection Agency, William Jefferson Clinton North Building, Mailcode 3206A, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number, (202) 564–6153; email address, *Ross.Jon@epa.gov*.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301; Federal Information Security Modernization Act (Pub. L. 104–106, sec. 5113); Electronic Government Act (Pub. L. 104–347, sec. 203); the Paperwork Reduction Act of 1995 (44 U.S.C. 3501); and the Government Paperwork Elimination Act (Pub. L. 105–277, 44 U.S.C. 3504); Federal Property and Administrative Act of 1949, as amended.

PURPOSE OF THE SYSTEM:

The purpose of the Personnel Security System is to assist the members of the Security Management Division with tracking the documentation associated with background investigations for potential and current Federal and non-Federal personnel working for EPA.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who require access to EPA-controlled facilities, information technology systems, or information classified in the interest of national security, including applicants for employment or to work on a contract, grant etc. Federal employees, contractors, grantees, students, interns, volunteers, other non-Federal employees and individuals formerly in any of these positions. The system does not apply to occasional visitors or short-term guests to whom the Agency will issue temporary identification.

CATEGORIES OF RECORDS IN THE SYSTEM:

Employee name, social security number (SSN), date and place of birth, organization, office and home addresses, office and home and cell phone, job series, pay grade, previous employments, overseas travel, military service, credit information, fingerprint results, OPM's background investigation reports, driver's license information, passport information, photograph, emergency contact, foreign passport, foreign travel, foreign involvement, foreign contacts, ownership of foreign property, foreign bank accounts and arrests in foreign countries.

RECORD SOURCE CATEGORIES:

The sources of data within PSS 2.0 are from internal EPA systems such as the Human Resources Line of Business (HRLoB) and the General Service Administration (GSA) external system, USAccess, and from external sources such as vendors, applicants and onboard personnel. The HRLoB SORN is EPA–1 and the USAccess SORN is GSA/GOVT–7.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

The following routine uses are both related to and compatible with the original purpose for which the information was collected. General routine uses A, B, C, D E, F, G, H, I, J, and K apply to this system (73 FR 2245). In addition, the two routine uses below (L and M) are required by M–17–12.

L. Disclosure to Persons or Entities in Response to an Actual or Suspected Breach of Personally Identifiable Information. To appropriate agencies, entities, and persons when (1) the Agency suspects or has confirmed that there has been a breach of the system of records, (2) the Agency has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Agency (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Agency's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

M. Disclosure to assist another agency in its efforts to respond to a breach. To another Federal agency or Federal entity, when the Agency determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

The information collected within PSS 2.0 is maintained and stored in the database located at NCC. These records are maintained electronically on computer storage devices such as computer tapes and disks. Backup will be maintained at a disaster recovery site. Computer records are maintained in a secure password protected environment. Access to computer records is limited to those who have a need to know. Permission level assignments will allow users access only to those functions for which they are authorized. All records are maintained in secure, access-controlled areas or buildings.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Personal information will be retrieved by SSN, name, date of birth, email address, personal identification number or background investigation case number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are retained and disposed of in accordance with NARA records retention schedules appropriate to the retention of background investigation related data, as well as EPA's Records Schedule 1008.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Security controls used to protect personal sensitive data in PSS 2.0 are commensurate with those required for an information system rated MODERATE for confidentiality, integrity, and availability, as prescribed in NIST Special Publication, 800–53, ''Recommended Security Controls for Federal Information Systems,'' Revision 4.

ADMINISTRATIVE SAFEGUARDS:

Access to PSS 2.0 requires two-factor authentication accomplished by using Personal Identity Verification (PIV) cards that are issued to all personnel based on the requirements of Homeland Security Presidential Directive 12 (HSPD 12).

When a user is logged into PSS 2.0, they are asked by the system to confirm that they still want to remain logged in. If there is no response, or after 15 minutes of inactivity, the user is automatically logged out of the system. Personnel are instructed to lock their computer when they leave their desks. Personnel receive annual Privacy Act awareness training and are regularly reminded about appropriate SPII and PII handling procedures.

In addition to the agency's Rules of Behavior and Privacy Act training that personnel undergo, PSS users are required to sign a PSS-specific Rules of Behavior document prior to their access being granted to the system.

Contracting Officer's Representatives (CORs) will be receiving SPII/PII as a normal part of their operations. The COR's user guide provides confirmation of how SPII/PII should be handled, and the following is an excerpt of that guide:

''BE AWARE THAT YOU ARE HANDLING SENSITIVE PERSONALLY IDENTIFIABLE INFORMATION (SPII) and need to do so under the following guidelines, which will help prevent privacy breaches by ensuring the COR, who has a need to know the information, is the only individual to see the PII/SPII:

- The COR will instruct the vendor to send the requested information (name, email address, SSN) by email with the COR as the only EPA email recipient.
- The COR will enter the information into PSS 2.0 and will then delete the email.
- To properly delete the email, press the Shift key and the Delete key at the same time—this will fully remove the email, so it isn't even in the Deleted Items folder.
- If the COR replies to the email, the COR will ensure that all SPII and PII in their email response is removed prior to hitting Send.
- The COR will not save or print the email in any form.
- The COR will not forward the email to others.''

TECHNICAL SAFEGUARDS:

Access to the data is strictly controlled and is limited to those with an operational need to access the information. Access is granted and managed by PSS 2.0 Administrators. A ''least-privilege'' role-based access system is employed that restricts access to data on a ''need-to-know'' basis; access to the data is limited to those with an operational need to access the information. Additionally, all web-based access to the application requires multi-factor authentication.

PHYSICAL SAFEGUARDS:

EPA employees and contractors involved in the management, design, development, implementation and execution of the program will have monitored access to the application. Only individuals who have the proper authorization and who perform functions related to PSS 2.0 are allowed to access any information. Entry to the EPA facility and within the facility to specific spaces at the NCC is achieved using HSPD–12 PIV cards on door readers. PIV cards are only issued to personnel who have met EPA's initial security screening requirements. Security Guards at all entrances confirm that the PIV card is valid, unexpired and reflects the identity of the card holder. Entry to the server rooms is only available to personnel using their PIV cards on door readers, where those personnel have been approved for elevated access (meaning they have undergone a more rigorous security screening). The NCC maintains an Access Control List to ensure access to server rooms is limited to approved personnel only.

RECORD ACCESS PROCEDURES:

Any individual who wants access to his or her record, should make a written request to the EPA Attn: Privacy Officer, MC2831T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.

CONTESTING RECORD PROCEDURES:

Requests for correction or amendment must identify the record to be changed and the corrective action sought. Complete EPA Privacy Act procedures are described in EPA's Privacy Act regulations at 40 CFR part 16.

NOTIFICATION PROCEDURE:

Any individual who wants to know whether this system of records contains a record about him or her, should make a written request to the EPA, Attn: Privacy Officer, MC2831T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

Under 5 U.S.C. 552a(k)(1), (k)(2), and (k)(5), the Personnel Security System is exempt from the following provisions of the Privacy Act of 1974 as amended, subject to the limitations set forth in this subsection; 5 U.S.C. 552a(c)(3); (d)(2), (d)(3), and (d)(4); (e)(1), and (f)(2) through (5). Although the Personnel Security System has been exempted, EPA may, in its discretion, fully grant individual requests for access and correction if it determines that the exercise of these rights will not interfere with an interest that the exemption is intended to protect.

HISTORY:

The security files were previously covered under Office of Administrative Services Information System (OASIS) EPA 41 **Federal Register** (FR) Volume 71, Number 169, FR DOC No: 06–7319 until 2019 and is being transferred to this existing PSS 2.0 SORN to include all exemptions and provisions.

Vaughn Noga,

Senior Agency Official for Privacy.

[FR Doc. 2020–11356 Filed 5–28–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2014–0738; FRL–10009–62–OAR]

Notice of Request for Approval of Alternative Means of Emission Limitation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice and request for comments.

SUMMARY: This action provides public notice and solicits comment on the alternative means of emission limitation (AMEL) request from Lyondell Chemical Company (Lyondell), under the Clean Air Act (CAA), for the multi-point ground flares (MPGFs) at its Channelview chemical plant in Houston, Texas.

DATES:

Comments: Comments must be received on or before July 13, 2020.

Public hearing: If anyone contacts us requesting a public hearing on or before June 3, 2020, the EPA will hold a virtual public hearing on June 15, 2020. Please refer to the **SUPPLEMENTARY INFORMATION** section for additional information on the public hearing.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OAR–2014–0738, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- *Email: a-and-r-docket@epa.gov.* Include Docket ID No. EPA–HQ–OAR–2014–0738 in the subject line of the message.

Instructions. Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2014–0738, at *https://www.regulations.gov/*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*, *Regulations.gov* is our preferred method of receiving comments. All submissions received must include the Docket ID No. for this rulemaking. For detailed instructions on sending comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of

this document. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room was closed to public visitors on March 31, 2020, 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 comments via *https://www.regulations.gov/* or email, as there is a temporary suspension of mail delivery to the EPA, and no hand deliveries are currently accepted. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets*.

If requested, the virtual hearing will be held on June 15, 2020. The hearing will convene at 9:00 a.m. Eastern Standard Time (EST) and will conclude at 3:00 p.m. EST. The EPA will announce further details on the virtual public hearing website at *https://www.epa.gov/stationary-sources-air-pollution/alternative-means-emission-limitation-flares*. Refer to the **SUPPLEMENTARY INFORMATION** section below for additional information.

FOR FURTHER INFORMATION CONTACT: For questions about this action, contact Ms. Angela Carey, Sector Policies and Programs Division (E143–01), Office of Air Quality Planning and Standards (OAQPS), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–2187; fax number: (919) 541–0516; and email address: *carey.angela@epa.gov*.

SUPPLEMENTARY INFORMATION:

Participation in virtual public hearing. Please note that the EPA is deviating from its typical approach because the President has declared a national emergency. Due to the current Centers for Disease Control and Prevention (CDC) recommendations, as well as state and local orders for social distancing to limit the spread of COVID–19, the EPA cannot hold in-person public meetings at this time.

If a public hearing is requested, the EPA will begin pre-registering speakers for the hearing upon publication of this document in the **Federal Register**. To register to speak at the virtual hearing, please use the online registration form available at *https://www.epa.gov/stationary-sources-air-pollution/alternative-means-emission-limitation-flares* or contact Virginia Hunt at 919–541–0832 or by email at *hunt.virginia@epa.gov* to register to speak at the virtual hearing. The last day to pre-register to speak at the hearing will be June 11, 2020. On June 12, 2020, the EPA will post a general agenda for the hearing that will list pre-registered speakers in approximate order at: *https://www.epa.gov/stationary-sources-air-pollution/alternative-means-emission-limitation-flares*.

The EPA will make every effort to follow the schedule as closely as possible on the day of the hearing; however, please plan for the hearing to run either ahead of schedule or behind schedule.

Each commenter will have 5 minutes to provide oral testimony. The EPA encourages commenters to provide the EPA with a copy of their oral testimony electronically (via email) by emailing it to Angela Carey and Virginia Hunt. The EPA also recommends submitting the text of your oral testimony as written comments to the rulemaking docket.

The EPA may ask clarifying questions during the oral presentations but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as oral testimony and supporting information presented at the public hearing.

Please note that any updates made to any aspect of the hearing will be posted online at *https://www.epa.gov/stationary-sources-air-pollution/alternative-means-emission-limitation-flares*. While the EPA expects the hearing to go forward as set forth above, if requested, please monitor our website or contact Virginia Hunt at 919–541–0832 or *hunt.virginia@epa.gov* to determine if there are any updates. The EPA does not intend to publish a document in the **Federal Register** announcing updates.

If you require the services of a translator or a special accommodation such as audio description, please pre-register for the hearing with Virginia Hunt and describe your needs by June 5, 2020. The EPA may not be able to arrange accommodations without advance notice.

Docket. The EPA has established a docket for this rulemaking under Docket ID No. EPA–HQ–OAR–2014–0738. All documents in the docket are listed in *Regulations.gov*. Although listed, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy. Publicly available docket materials are available electronically in *Regulations.gov*.

Instructions. Direct your comments to Docket ID No. EPA–HQ–OAR–2014–0738. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *https://www.regulations.gov/,* including any personal information provided, unless the comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statue. This type of information should be submitted by mail as discussed below.

The EPA may publish any comment received to its public docket. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets*.

The *https://www.regulations.gov/* website allows you to submit your comment anonymously, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *https://www.regulations.gov/,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any digital storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *https://www.epa.gov/dockets*.

The EPA is temporarily suspending its Docket Center and Reading Room for public visitors to reduce the risk of transmitting COVID–19. Written

comments submitted by mail are temporarily suspended and no hand deliveries will be accepted. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov/*. For further information and updates on EPA Docket Center services, please visit us online at *https://www.epa.gov/dockets*.

The EPA continues to carefully and continuously monitor information from the CDC, local area health departments, and our Federal partners so that we can respond rapidly as conditions change regarding COVID–19.

Submitting CBI. Do not submit information containing CBI to the EPA through *https://www.regulations.gov/* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, mark the outside of the digital storage media as CBI and then identify electronically within the digital storage media the specific information that is claimed as CBI. In addition to one complete version of the comments that includes information claimed as CBI, you must submit a copy of the comments that does not contain the information claimed as CBI directly to the public docket through the procedures outlined in *Instructions* section above. If you submit any digital storage media that does not contain CBI, mark the outside of the digital storage media clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and the EPA's electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2. Send or deliver information identified as CBI only to the following address: OAQPS Document Control Officer (C404–02), OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA–HQ–OAR–2014–0738. Note that written comments containing CBI and submitted by mail may be delayed and no hand deliveries will be accepted.

Acronyms and abbreviations. We use multiple acronyms and terms in this document. While this list may not be exhaustive, to ease the reading of this document and for reference purposes, the EPA defines the following terms and acronyms here:

AMEL alternative means of emission limitation
BTU/scf British thermal units per standard cubic foot
CAA Clean Air Act
CBI Confidential Business Information
CFR Code of Federal Regulations
EPA Environmental Protection Agency
Eqn equation
HAP hazardous air pollutants
MPGF multi-point ground flare
NESHAP national emission standards for hazardous air pollutants
NHV net heating value
NHV_{cz} net heating value of combustion zone gas
NHV_{vg} net heating value of flare vent gas
NSPS new source performance standards
OAQPS Office of Air Quality Planning and Standards
POTBA propylene oxide tertiary butyl alcohol unit scf standard cubic feet
SKEC steam-assisted kinetic energy combustor
VOC volatile organic compounds

Organization of this document. The information in this document is organized as follows:

I. Background
II. Request for AMEL
A. Propylene Oxide Tertiary Butyl Alcohol Unit (POTBA) MPGFs
B. Information Supporting AMEL Request for POTBA MPGFs
III. AMEL for the POTBA MPGFs
IV. Request for Comments

I. Background

In this action, the U.S. Environmental Protection Agency (EPA) is soliciting comment on all aspects of this AMEL request by Lyondell, including the corresponding operating conditions that would demonstrate that the requested AMEL would achieve a reduction in emissions of volatile organic compounds (VOC) and hazardous air pollutants (HAP) at least equivalent to the reduction in emissions required by the applicable standards in 40 CFR parts 60 and 63. Lyondell is requesting an AMEL for the MPGFs to be used at a new propylene oxide tertiary butyl alcohol (''POTBA'') unit at Lyondell's Channelview facility. According to Lyondell, the POTBA unit is subject to the new source performance standards (NSPS) and national emission standards for hazardous air pollutants (NESHAP) for source categories identified in Table 1 below. These NSPS and NESHAP incorporate the flare design and operating requirements in the 40 CFR parts 60 and 63 General Provisions (*i.e.,* 40 CFR 60.18(b) and 63.11(b)) into the individual subparts.

This AMEL request was submitted to the EPA because the MPGFs for the new POTBA unit would not be able to comply with the applicable flare tip velocity requirements in the General Provisions to 40 CFR parts 60 and 63. These maximum flare tip velocity requirements ensure that the flame does not ''lift off'' or separate from the flare tip, which could cause flame instability and/or potentially result in a portion of the flare gas being released without proper combustion. Proper combustion for flares is considered to be 98-percent destruction efficiency or greater for organic HAP and VOC. The MPGFs in this AMEL request are designed to operate with tip exit velocities greater than those allowed in 40 CFR 60.18 and 63.11, while achieving ≥96.5-percent combustion efficiency and 98-percent destruction efficiency.

Provided below in Table 1 is a list of regulations, by subparts, that Lyondell has identified as applicable to the new POTBA unit's MPGFs described in this section above. The middle column identifies the requirement in each cited NSPS or NESHAP that flares used to satisfy the NSPS or NESHAP must meet flare design and operating requirements in the 40 CFR parts 60 and 63 General Provisions (*i.e.,* 40 CFR 60.18(b) and 63.11(b)). Lyondell is seeking an AMEL for these flare requirements.

TABLE 1—SUMMARY OF APPLICABLE RULES TO EMISSIONS CONTROLLED BY MPGFS FOR THE POTBA

Applicable rules with vent streams going to control device(s)	Emission reduction requirements (allowing for use of a flare)	Provisions for alternative means of emission limitation
NSPS subpart VV	60.482–1 60.482–10(d)	60.484.
NSPS subpart VVa	60.482–1a 60.482–10a(d)	60.484a.
NSPS subpart III	60.612(b)	
NSPS subpart NNN	60.662(b)	
NSPS subpart RRR	60.702(b)	
NSPS subpart Kb	60.112b(a)(3)(ii)	60.114b.
NESHAP subpart V	61.242–1 61.242–11(d)	63.6(g).

TABLE 1—SUMMARY OF APPLICABLE RULES TO EMISSIONS CONTROLLED BY MPGFS FOR THE POTBA—Continued

Applicable rules with vent streams going to control device(s)	Emission reduction requirements (allowing for use of a flare)	Provisions for alternative means of emission limitation
NESHAP subparts F, G ..	63.102, 63.112(e), 63.113(a)(1)(i), 63.116(a)(2), 63.116(a)(3), 63.119(e)(1), 63.120(e)(1) through (4), 63.126(b)(2)(i), 63.128(b), 63.139(c)(3), 63.139(d)(3), 63.145(j).	63.6(g).
NESHAP subpart H	63.162	63.162(b).
	63.172(d), 63.180(e)	63.177.

The provisions in each NSPS and NESHAP Table 1, cited above, which ensure that flares meet certain specific operating requirements when used to satisfy the requirements of the NSPS or NESHAP, were established as work practice standards pursuant to CAA sections 111(h)(1) or 112(h)(1). For standards established according to these provisions, CAA sections 111(h)(3) and 112(h)(3) allow the EPA to permit the use of an AMEL by a source if, after notice and opportunity for comment,[1] it is established to the Administrator's satisfaction that such an AMEL will achieve emissions reductions at least equivalent to the reductions required under the applicable CAA section 111(h)(1) or 112(h)(1) standards. As noted in Table 1 of this document, many of the identified NSPS and NESHAP also include specific regulatory provisions allowing sources to request an AMEL.

Lyondell submitted an AMEL request to operate above the applicable maximum permitted velocity requirements for flares in the General Provisions in 40 CFR parts 60 and 63. Lyondell provided information that the flare designs for the POTBA MPGFs achieve a reduction in emissions at least equivalent to the reduction in emissions for flares complying with the applicable General Provisions requirements. Lyondell's AMEL request was submitted on July 9, 2019, according to the framework for pressure assisted MPGFs that was published in the **Federal Register** on April 21, 2016 (see 81 FR 23486). The MPGF designs in this request are multi-point tip designs which employ large numbers of tips at heights close to ground level. The EPA has reviewed this request and has deemed the application to be complete. For further information on Lyondell's AMEL requests, see supporting materials from Lyondell at Docket ID No. EPA–HQ–OAR–2014–0738.

[1] CAA section 111(h)(3) requires that the EPA provide an opportunity for a hearing.

II. Request for AMEL

A. Propylene Oxide Tertiary Butyl Alcohol Unit (POTBA) MPGFs

Lyondell is seeking an AMEL for operating MPGFs at its new POTBA unit during both routine and emergency vent gas flows. Specifically, the AMEL is for a small MPGF for routine vent gas flows, as well as a separate larger MPGF for emergency vent gas flows.

Both MPGFs are designed as an integral part of a larger control system that will control waste gases in stages. Vent gases are captured and routed back into the process and/or fuel systems to minimize environmental impact. Gases not returned back to process or to fuel gas systems are directed to a control system with two separate dispositions: A low pressure (LP) MPGF and a high pressure (HP) MPGF. The LP continuous or routine stages for the POTBA MPGF will be in one burner field and the HP emergency stages will be in a separate burner field. The planned POTBA LP MPGF is designed to have two stages with a total of 12 John Zink SKEC steam assist burners. Each steam assisted burner will have a natural gas fired direct spark electronic ignition pilot. Each stage will also have at least two pilots with a continuously lit pilot flame. The planned POTBA HP MPGF is designed to have nine stages with six John Zink SKEC steam assist burners and 694 John Zink LRGO–HC pressure assist burners. Each steam assisted burner will have a natural gas fired direct spark electronic ignition pilot. Each stage of the pressure assisted burners will have two continuously lit pilots. As mentioned in section I above, both MPGFs are designed to operate with tip exit velocities greater than those allowed in 40 CFR 60.18 and 63.11, while achieving ≥96.5-percent combustion efficiency and 98-percent destruction efficiency.

B. Information Supporting AMEL Request for POTBA MPGFs

As mentioned in section I above, Lyondell provided the information specified in the 2016 flare AMEL framework to support its AMEL request. The information provided by Lyondell includes: (1) Details on the project scope and background; (2) information on applicable NSPS and NESHAP; (3) flare test data on destruction efficiency/combustion efficiency; (4) flare stability testing data; (5) flare cross-light testing data; (6) information on flare reduction considerations; and (7) information on appropriate flare monitoring and operating conditions. (For further information on the supporting materials provided, see Docket ID No. EPA–HQ–OAR–2014–0738.)

Information supplied by Lyondell indicates that both MPGFs can achieve ≥96.5-percent combustion efficiency and 98-percent destruction efficiency if operated under certain conditions. Generally, testing of burners for the vent gas mixture determined to be representative of the flare operation was used to set the appropriate combustion zone net heating value (NHV_{cz}) minimum limit. However, EPA recently proposed amendments to the Ethylene Production NESHAP, 40 CFR part 63, subpart YY (84 FR 54278, October 9, 2019), and the Miscellaneous Organic NESHAP (MON), 40 CFR part 63, subpart FFFF (84 FR 69182, December 17, 2019), for MPGFs. These rules proposed that owners or operators of MPGF: (1) Maintain an NHV_{cz} ≥800 British thermal units per standard cubic foot (BTU/scf); (2) continuously monitor the NHV_{cz} and flare vent gas flow rate; (3) continuously monitor for the presence of a pilot flame, and if cross-lighting is used on a particular stage of burners because there is no pilot on each burner, then continuously monitor to ensure that the stage has a minimum of two pilots per stage that will ignite all flare vent gases sent to that stage; (4) operate the MPGF with no visible emissions (except for 5 minutes during any 2 consecutive hours); (5) maintain a distance of no greater than 6 feet between any two burners in series on a stage of burners that do not have a continuously lit pilot; and (6) monitor to ensure staging valves for each stage of the MPGF operate properly so that the flare will control vent gases within the proper flow and pressure ranges based on the flare manufacturer's

recommendations. For the reasons stated in those two proposed rules, we are including in this document these same requirements as operating conditions for the requested AMEL, as specified in section III below.

III. AMEL for the POTBA MPGFs

Based upon our review of the AMEL request, we believe that, by complying with the operating conditions specified in Table 2 and accompanying paragraphs below, the MPGFs for the new POTBA at Lyondell's Channelview facility will achieve emission reductions at least equivalent to reduction in emissions being controlled by MPGFs complying with the flare requirements under the applicable NSPS and NESHAP identified in Table 1 of this document. We are seeking the public's input on this request. Specifically, the EPA seeks the public's input on the conditions specified in this document in the following paragraphs.

TABLE 2—PROPOSED ALTERNATIVE OPERATING CONDITIONS

AMEL submitted	Company	Affected facilities	Flare type(s)	Proposed alternative operating conditions
7/9/19	Lyondell	Channelview, TX, small MPGF for routine vent gas flows; and a separate larger MPGF for emergency vent gas flows.	MPGFs	≥800 BTU/scf NHV_{cz}.

(1) All MPGFs must be operated such that the combustion zone gas net heating value (NHV_{cz}) is ≥800 BTU/scf. Owners or operators must demonstrate compliance with the applicable NHV_{cz} on a 15-minute block average. Owners or operators must calculate and monitor for the NHV_{cz} according to the following:

(a) Calculation of NHV_{cz}

(i) If an owner or operator elects to use a monitoring system capable of continuously measuring (*i.e.,* at least once every 15 minutes), calculating, and recording the individual component concentrations present in the flare vent gas, NHV_{vg} shall be calculated using the following equation:

$$NHV_{vg} = \sum_{i=1}^{n} x_i NHV_i$$

(Eqn. 1)

Where:

NHV_{vg} = Net heating value of flare vent gas, BTU/scf.

Flare vent gas means all gas found just prior to the tip. This gas includes all flare waste gas (*i.e.,* gas from facility operations that is directed to a flare for the purpose of disposing the gas), flare sweep gas, flare purge gas, and flare supplemental gas, but does not include pilot gas.

i = Individual component in flare vent gas.

n = Number of components in flare vent gas.

x_i = Concentration of component i in flare vent gas, volume fraction.

NHV_i = Net heating value of component i determined as the heat of combustion where the net enthalpy per mole of offgas is based on combustion at 25 degrees Celsius (°C) and 1 atmosphere (or constant pressure) with water in the gaseous state from values published in the literature, and then the values are converted to a volumetric basis using 20 °C for ''standard temperature.'' Table 3 summarizes component properties including net heating values.

(ii) If the owner or operator uses a continuous net heating value monitor, the owner or operator may, at their discretion, install, operate, calibrate, and maintain a monitoring system capable of continuously measuring, calculating, and recording the hydrogen concentration in the flare vent gas. The owner or operator shall use the following equation to determine NHV_{vg} for each sample measured via the net heating value monitoring system.

$$NHV_{vg} = NHV_{measured} + 938x_{H2}$$

(Eqn. 2)

Where:

NHV_{vg} = Net heating value of flare vent gas, BTU/scf.

$NHV_{measured}$ = Net heating value of flare vent gas stream as measured by the continuous net heating value monitoring system,/scf.

x_{H2} = Concentration of hydrogen in flare vent gas at the time the sample was input into the net heating value monitoring system, volume fraction.

938 = Net correction for the measured heating value of hydrogen (1,212 -274), BTU/scf.

(iii) NHV_{cz} shall be calculated using Equation 3.

$$NHV_{cz} = \frac{Q_{vg} \times NHV_{vg} + Q_{ag} \times NHV_{ag}}{(Q_{vg} + Q_{ag})}$$

(Eqn. 3)

Where:

NHV_{cz} = Net heating value of combustion zone gas, BTU/scf.

NHV_{vg} = Net heating value of flare vent gas for the 15-minute block period as determined according to (1)(a)(i), BTU/scf.

Q_{vg} = Cumulative volumetric flow of flare vent gas during the 15-minute block period, scf.

Q_{ag} = Cumulative volumetric flow of assist gas during the 15-minute block period, standard cubic feet flow rate, scf.

NHV_{ag} = Net heating value of assist gas, BTU/scf; this is zero for air or for steam.

(b) For all flare systems specified in this document, the operator shall install, operate, calibrate, and maintain a monitoring system capable of continuously measuring the volumetric flow rate of flare vent gas (Q_{vg}), the volumetric flow rate of total assist steam (Q_s), the volumetric flow rate of total assist air (Q_a), and the volumetric flow rate of total assist gas (Q_{ag}).

(i) The flow rate monitoring systems must be able to correct for the temperature and pressure of the system and output parameters in standard conditions (*i.e.,* a temperature of 20 °C (68 °F) and a pressure of 1 atmosphere).

(ii) Mass flow monitors may be used for determining volumetric flow rate of flare vent gas provided the molecular weight of the flare vent gas is determined using compositional analysis so that the mass flow rate can be converted to volumetric flow at standard conditions using the following equation:

$$Q_{vol} = \frac{Q_{mass} \times 385.3}{MW_t}$$

(Eqn. 6)

Where:

Q_{vol} = Volumetric flow rate, scf/second (sec).

Q_{mass} = Mass flow rate, pounds per sec. 385.3 = Conversion factor, scf per pound-mole.

MW_t = Molecular weight of the gas at the flow monitoring location, pounds per pound-mole.

(c) For each measurement produced by the monitoring system used to comply with (1)(a)(ii), the operator shall determine the 15-minute block average as the arithmetic average of all measurements made by the monitoring system within the 15-minute period.

(d) The operator must follow the calibration and maintenance procedures according to Table 4. Total time spent on maintenance, instrument adjustments or checks to maintain precision and accuracy, and zero and span adjustments may not exceed 5

percent of the time the flare is receiving regulated material.

TABLE 3—INDIVIDUAL COMPONENT PROPERTIES

Component	Molecular formula	MW_i (pounds per pound-mole)	NHV_i (BTU/scf)	LFL_i (volume %)
Acetylene	C_2H_2	26.04	1,404	2.5
Benzene	C_6H_6	78.11	3,591	1.3
1,2-Butadiene	C_4H_6	54.09	2,794	2.0
1,3-Butadiene	C_4H_6	54.09	2,690	2.0
iso-Butane	C_4H_{10}	58.12	2,957	1.8
n-Butane	C_4H_{10}	58.12	2,968	1.8
cis-Butene	C_4H_8	56.11	2,830	1.6
iso-Butene	C_4H_8	56.11	2,928	1.8
trans-Butene	C_4H_8	56.11	2,826	1.7
Carbon Dioxide	CO_2	44.01	0	∞
Carbon Monoxide	CO	28.01	316	12.5
Cyclopropane	C_3H_6	42.08	2,185	2.4
Ethane	C_2H_6	30.07	1,595	3.0
Ethylene	C_2H_4	28.05	1,477	2.7
Hydrogen	H_2	2.02	*1,212	4.0
Hydrogen Sulfide	H_2S	34.08	587	4.0
Methane	CH_4	16.04	896	5.0
Methyl-Acetylene	C_3H_4	40.06	2,088	1.7
Nitrogen	N_2	28.01	0	∞
Oxygen	O_2	32.00	0	∞
Pentane+ (C5+)	C_5H_{12}	72.15	3,655	1.4
Propadiene	C_3H_4	40.06	2,066	2.16
Propane	C_3H_8	44.10	2,281	2.1
Propylene	C_3H_6	42.08	2,150	2.4
Water	H_2O	18.02	0	∞

*The theoretical net heating value for hydrogen is 274 BTU/scf, but for these purposes flare, a net heating value of 1,212 BTU/scf shall be used.

TABLE 4—ACCURACY AND CALIBRATION REQUIREMENTS

Parameter	Accuracy requirements	Calibration requirements
Flare Vent Gas Flow Rate.	±20 percent of flow rate at velocities ranging from 0.1 to 1 foot per sec. ±5 percent of flow rate at velocities greater than 1 foot per sec.	Evaluate performance biennially (every 2 years) and following any period of more than 24 hours throughout which the flow rate exceeded the maximum rated flow rate of the sensor, or the data recorder was off scale. Check all mechanical connections for leakage monthly. Visually inspect and check system operation every 3 months, unless the system has a redundant flow sensor. Select a representative measurement location where swirling flow or abnormal velocity distributions due to upstream and downstream disturbances at the point of measurement are minimized.
Flow Rate for All Flows Other Than Flare Vent Gas.	±5 percent over the normal range of flow measured or 1.9 liters per minute (0.5 gallons per minute), whichever is greater, for liquid flow.	Conduct a flow sensor calibration check at least biennially (every 2 years); conduct a calibration check following any period of more than 24 hours throughout which the flow rate exceeded the manufacturer's specified maximum rated flow rate or install a new flow sensor.
	±5 percent over the normal range of flow measured or 280 liters per minute (10 cubic feet per minute), whichever is greater, for gas flow.	At least quarterly, inspect all components for leakage, unless the continuous parameter monitoring system (CPMS) has a redundant flow sensor.
	±5 percent over the normal range measured for mass flow.	Record the results of each calibration check and inspection. Locate the flow sensor(s) and other necessary equipment (such as straightening vanes) in a position that provides representative flow; reduce swirling flow or abnormal velocity distributions due to upstream and downstream disturbances.

TABLE 4—ACCURACY AND CALIBRATION REQUIREMENTS—Continued

Parameter	Accuracy requirements	Calibration requirements
Pressure	±5 percent over the normal range measured or 0.12 kilopascals (0.5 inches of water column), whichever is greater.	Review pressure sensor readings at least once a week for straight-line (unchanging) pressure and perform corrective action to ensure proper pressure sensor operation if blockage is indicated. Evaluate performance annually and following any period of more than 24 hours throughout which the pressure exceeded the maximum rated pressure of the sensor, or the data recorder was off scale. Check all mechanical connections for leakage monthly. Visually inspect all components for integrity, oxidation, and galvanic corrosion every 3 months, unless the system has a redundant pressure sensor. Select a representative measurement location that minimizes or eliminates pulsating pressure, vibration, and internal and external corrosion.
Net Heating Value by Calorimeter.	±2 percent of span	Calibrate according to manufacturer's recommendations at a minimum. Temperature control (heated and/or cooled as necessary) the sampling system to ensure proper year-round operation. Where feasible, select a sampling location at least 2 equivalent diameters downstream from and 0.5 equivalent diameters upstream from the nearest disturbance. Select the sampling location at least 2 equivalent duct diameters from the nearest control device, point of pollutant generation, air in-leakages, or other point at which a change in the pollutant concentration or emission rate occurs.
Net Heating Value by Gas Chromatograph.	As specified in Performance Standard (PS) 9 of 40 CFR part 60, appendix B.	Follow the procedure in PS 9 of 40 CFR part 60, appendix B, except that a single daily mid-level calibration check can be used (rather than triplicate analysis), the multi-point calibration can be conducted quarterly (rather than monthly), and the sampling line temperature must be maintained at a minimum temperature of 60 °C (rather than 120 °C).
Hydrogen Analyzer.	±2 percent over the concentration measured, or 0.1 volume, percent, whichever is greater.	Specify calibration requirements in your site specific CPMS monitoring plan. Calibrate according to manufacturer's recommendations at a minimum. Specify the sampling location at least 2 equivalent duct diameters from the nearest control device, point of pollutant generation, air inleakages, or other point at which a change in the pollutant concentration occurs.

(2) The flare system must be operated with a flame present at all times when in use. Additionally, each stage must have at least two pilots with a continuously lit pilot flame. Each pilot flame must be continuously monitored by a thermocouple or any other equivalent device used to detect the presence of a flame. The time, date, and duration of any complete loss of pilot flame on any of the burners must be recorded. Each monitoring device must be maintained or replaced at a frequency in accordance with the manufacturer's specifications.

(3) The MPGF system shall be operated with no visible emissions except for periods not to exceed a total of 5 minutes during any 2 consecutive hours. A video camera that is capable of continuously recording (*i.e.,* at least one frame every 15 seconds with time and date stamps) images of the flare flame and a reasonable distance above the flare flame at an angle suitable for visible emissions observations must be used to demonstrate compliance with this requirement. The owner or operator must provide real-time video surveillance camera output to the control room or other continuously manned location where the video camera images may be viewed at any time.

(4) The operator of the MPGF system shall install and operate pressure monitor(s) on the main flare header, as well as a valve position indicator monitoring system capable of monitoring and recording the position for each staging valve to ensure that the flare operates within the range of tested conditions or within the range of the manufacturer's specifications. The pressure monitor shall meet the requirements in Table 4. Total time spent on maintenance periods, instrument adjustments or checks to maintain precision and accuracy, and zero and span adjustments may not exceed 5 percent of the time the flare is receiving regulated material.

(5) Recordkeeping Requirements

(a) All data must be recorded and maintained for a minimum of 3 years or for as long as required under applicable rule subpart(s), whichever is longer.

(6) Reporting Requirements

(a) The information specified in sections III (6)(b) and (c) below must be reported in the timeline specified by the applicable rule subpart(s) for which the MPGFs will control emissions.

(b) Owners or operators shall include the final AMEL operating requirements for each flare in their initial Notification of Compliance status report.

(c) The owner or operator shall notify the Administrator of periods of excess emissions in their Periodic Reports. The notification shall include:

(i) Records of each 15-minute block for both MPGFs during which there was at least 1 minute when regulated material was routed to the flare and a complete loss of pilot flame on a stage of burners occurred, and for both MPGFs, records of each 15-minute block during which there was at least 1 minute when regulated material was routed to the flare and a complete loss of pilot flame on an individual burner occurred.

(ii) Records of visible emissions events (including the time and date stamp) that exceed more than 5 minutes in any 2-hour consecutive period.

(iii) Records of each 15-minute block period for which an applicable combustion zone operating limit (*i.e.,*

NHV_{cz}) is not met for the flare when regulated material is being combusted in the flare. Indicate the date and time for each period, the NHV_{cz} operating parameter for the period, the type of monitoring system used to determine compliance with the operating parameters (*e.g.,* gas chromatograph or calorimeter), and also indicate which high-pressure stages were in use.

(iv) Records of when the pressure monitor(s) on the main flare header show the flare burners are operating outside the range of tested conditions or outside the range of the manufacturer's specifications. Indicate the date and time for each period, the pressure measurement, the stage(s) and number of flare burners affected, and the range of tested conditions or manufacturer's specifications.

(v) Records of when the staging valve position indicator monitoring system indicates a stage of the flare should not be in operation and is or when a stage of the flare should be in operation and is not. Indicate the date and time for each period, whether the stage was supposed to be open, but was closed, or vice versa, and the stage(s) and number of flare burners affected.

IV. Request for Comments

We solicit comments on all aspects of Lyondell's requests for approval of an AMEL for MPGFs to be used to comply with the standards specified in Table 1 of this document. We specifically seek comment regarding whether or not the MPGF operating requirements listed in section III above will achieve emission reductions at least equivalent to emissions being controlled by flares complying with the applicable flare requirements in 40 CFR 60.18(b) and 63.11(b).

Dated: May 22, 2020.

Panagiotis Tsirigotis,

Director, Office of Air Quality Planning and Standards.

[FR Doc. 2020–11541 Filed 5–28–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2020–0052; FRL–10009–88]

Pesticide Product Registration; Receipt of Applications for New Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before June 29, 2020.

ADDRESSES: Submit your comments, identified by the docket identification (ID) number and the File Symbol of the EPA registration Number of interest as shown in the body of this document, 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 Confidential Business Information (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 *https://www.epa.gov/dockets/where-send-comments-epa-dockets*.

Please note that due to the public health emergency the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), main telephone number: (703) 305–7090, email address: *RDFRNotices@epa.gov*. The mailing address for each contact person is: Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. As part of the mailing address, include the contact person's name, division, and mail code. The division to contact is listed at the end of each application summary.

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).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets*.

II. Registration Applications

EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the provisions of FIFRA section 3(c)(4) (7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by the Agency on these applications.

Notice of Receipt—New Uses

1. *EPA Registration Numbers:* 279–9586, 279–9596, 279–9597, and 279–9598. *Docket ID number:* EPA–HQ–OPP–2019–0384. *Applicant:* FMC Corporation, 2929 Walnut Street, Philadelphia, PA 19104. *Active ingredient:* Indoxacarb. *Product type:* Insecticide. *Proposed use:* Tobacco. *Contact:* RD.

2. *EPA Registration Numbers:* 7969–185, 7969–258, and 7969–310. *Docket ID number:* EPA–HQ–OPP–2020–0227. *Applicant:* BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709–3528. *Active ingredient:*

Pyraclostrobin. *Product type:* Fungicide. *Proposed use:* Pomegranate. *Contact:* RD.

3. *EPA Registration Numbers:* 71711–16; 71711–20; 71711–21. *Docket ID number:* EPA–HQ–OPP–2020–0235. *Applicant:* NICHINO AMERICA, INC., 4550 Linden Hill Road, Suite 501, Wilmington, DE 19808. *Active ingredient:* Buprofezin. *Product type:* Insecticide. *Proposed uses:* Bushberry subgroup 13–07B, except blueberry, lowbush, lingonberry, and gooseberry; French bean, edible podded; garden bean, edible podded; green bean, edible podded; scarlet runner bean, edible podded; snap bean edible podded; kidney bean, edible podded; navy bean, edible podded; wax bean, edible podded; asparagus bean, edible podded; Catjang bean, edible podded; Chinese longbean, edible podded; cowpea, edible podded; moth bean, edible podded; mung bean, edible podded; rice bean, edible podded; urd bean, edible podded; yardlong bean, edible podded; goa bean, edible podded; guar bean, edible podded; jackbean, edible podded; lablab bean, edible podded; vegetable soybean, edible podded; sword bean, edible podded; winged pea, edible podded; velvet bean, edible podded. *Contact:* RD.

Authority: 7 U.S.C. 136 *et seq.*

Dated: May 13, 2020.

Delores Barber,

Director, Information Technology and Resources Management Division, Office of Pesticide Programs.

[FR Doc. 2020–11572 Filed 5–28–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9051–1]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS)

Filed May 18, 2020, 10 a.m. EST Through May 22, 2020, 11:59 p.m. EST

Pursuant to 40 CFR 1506.9.

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

EIS No. 20200109, Final, USAF, OH, Wright-Patterson Air Force Base Housing Program, Review Period Ends: 06/29/2020, Contact: Michael Ackerman 210–925–2741.

EIS No. 20200110, Draft, USA, GA, Fort Benning Heavy Off-Road Mounted Maneuver Training Area, Comment Period Ends: 07/13/2020, Contact: Mr. John Brown 706–545–7549.

EIS No. 20200111, Draft, CHSRA, CA, Burbank to Los Angeles Project Section Draft Environmental Impact Report/Environmental Impact Statement, Comment Period Ends: 07/13/2020, Contact: Dan McKell 916–330–5668.

EIS No. 20200113, Final, DOT, TX, Dallas to Houston High-Speed Rail, Review Period Ends: 06/29/2020, Contact: Kevin Wright 202–493–0845.

Dated: May 26, 2020.

Cindy S. Barger,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2020–11613 Filed 5–28–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2020–0052; FRL–10009–31]

Pesticide Product Registrations; Receipt of Applications for New Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before June 29, 2020.

ADDRESSES: Submit your comments, identified by the docket identification (ID) number and the EPA Registration Number of interest as shown in the body of this document, 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 Confidential Business Information (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 *https://www.epa.gov/dockets/where-send-comments-epa-dockets.*

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

Please note that, due to the public health emergency, the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information, and the current status of the EPA/DC and Reading Room, please visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *BPPDFRNotices@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).

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

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI

information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets.*

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, EPA seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. Registration Applications

EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the provisions of FIFRA section 3(c)(4) (7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by EPA on these applications. EPA received the following applications to register new uses for pesticide products containing currently registered active ingredients:

1. *EPA Registration Number:* 100–1469. *Docket ID number:* EPA–HQ–OPP–2019–0691. *Applicant:* Syngenta Crop Protection, LLC, 410 South Swing Rd., Greensboro, NC 27409. *Active ingredient: Aspergillus flavus* strain NRRL 21882. *Product type:* Fungicide. *Proposed use:* All food and feed commodities of almond; corn, field; corn, pop; corn, sweet; peanut; and pistachio. Note: In the **Federal Register** of March 2, 2020 (85 FR 12285) (FRL–10004–59), EPA announced receipt of an application to amend this pesticide product to add applications to almond and pistachio as new uses. Since that time, the applicant provided an associated petition to amend the currently existing *Aspergillus flavus* strain NRRL 21882 tolerance exemption to cover all food and feed commodities of almond; corn, field; corn, pop; corn, sweet; peanut; and pistachio. Although the applicant is still proposing to amend the pesticide product to add only applications to almond and pistachio as new uses (applications to corn and peanut are already registered uses), EPA is republishing its receipt of this application to make it clear that all the food and feed commodities of the aforementioned crops are intended be covered with applications of the product and to give the public an opportunity to comment on this clarifying information.

2. *EPA Registration Number:* 279–3618. *Docket ID number:* EPA–HQ–OPP–2017–0187. *Applicant:* FMC Corporation, 2929 Walnut St., Philadelphia, PA 19104. *Active ingredients: Bacillus licheniformis* strain FMCH001 and *Bacillus subtilis* strain FMCH002. *Product type:* Fungicide and nematicide. *Proposed use:* In-furrow application. Note: In the **Federal Register** of May 5, 2020 (85 FR 26684) (FRL–10008–46), EPA announced receipt of an application to amend this pesticide product to add seed treatment as a new use. Since that time, EPA noticed that it presented the new use as seed treatment instead of in-furrow application. In order to give the public an opportunity to comment on this corrected information, EPA is republishing its receipt of this application with an updated and accurate description.

(Authority: 7 U.S.C. 136 *et seq.*)

Dated: May 13, 2020.

Robert McNally,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 2020–11585 Filed 5–28–20; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK

Notice of Open Meeting of the Advisory Committee of the Export-Import Bank of the United States (EXIM)

Time and Date: Thursday, June 4, 2020 from 1:00–4:00 p.m. EDT.

Place: The meeting will be held via teleconference and audio-only webinar.

Agenda: Discussion of EXIM policies and programs and comments for inclusion in EXIM's Report to the U.S. Congress on Global Export Credit Competition.

Public Participation: The meeting will be open to public participation and time will be allotted for questions or comments submitted online. Members of the public may also file written statements before or after the meeting to *external@exim.gov.* Interested parties may register for the meeting at *https://attendee.gotowebinar.com/register/8637174416610897679.*

Further Information: For further information, contact the Office of External Engagement at *external@exim.gov.*

Joyce Stone,

Assistant Corporate Secretary.

[FR Doc. 2020–11584 Filed 5–28–20; 8:45 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK

Notice of Open Meeting of the Sub-Saharan Africa Advisory Committee of the Export-Import Bank of the United States (EXIM)

Time and Date: Tuesday, June 16, 2020 from 1:00–2:00 p.m. EDT.

Place: The meeting will be held via teleconference and audio-only webinar.

Agenda: Discussion of EXIM Bank policies and programs designed to support the expansion of financing support for U.S. manufactured goods and services in Sub-Saharan Africa.

Public Participation: The meeting will be open to public participation and time will be allotted for questions or comments submitted online. Members of the public may also file written statements before or after the meeting to *external@exim.gov.* Interested parties may register for the meeting at *https://attendee.gotowebinar.com/register/3240658097788674319.*

Further Information: For further information, contact the Office of External Engagement at *external@exim.gov.*

Joyce Stone,

Assistant Corporate Secretary.

[FR Doc. 2020–11579 Filed 5–28–20; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0222, FR No. 16787]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: 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; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; 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; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

DATES: Written comments should be submitted on or before July 28, 2020. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION: The FCC 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, and as required by the PRA of 1995 (44 U.S.C. 3501–3520), the FCC invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: 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; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; 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; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

OMB Control No.: 3060–0222.

Title: Section 97.213, Telecommand of an Amateur Station.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for profit entities.

Number of Respondents and Responses: 40,000 respondents and 40,000 responses.

Estimated Time per Response: 5 minutes (.084 hours).

Frequency of Response: Third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is approved under 47 U.S.C. 303, 151–155, 301–609.

Total Annual Burden: 3,360 hours.

Annual Cost Burden: No cost.

Privacy Act Impact Assessment: Yes. Respondents may request materials or information submitted to the Commission be withheld from public inspection under 47 CFR 0.459 of the FCC rules.

The respondents' telephone numbers are collected in the Commission's Universal Licensing System (ULS) database and are covered under the System of Records Notice (SORN), FCC/WTB–1, ''Wireless Services Licensing Records.''

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information except for respondents' telephone numbers which are not made available to the public and are covered under FCC/WTB–1, ''Wireless Services Licensing Records.''

Needs and Uses: The third party disclosure requirement contained in 47 CFR 97.213 consists of posting a photocopy of the amateur station license, a label with the name, address, and telephone number of the station licensee, and the name of at least one authorized control operator in a conspicuous place at the station location. This requirement is necessary so that quick resolution of any harmful interference problems can be identified and to ensure that the station is operating in accordance with the Communications Act of 1934, as amended.

This information is used by FCC personnel during inspections and investigations to determine who is responsible for the proper operation of the remotely controlled station. In the absence of this third party disclosure requirement, field inspections and investigations related to harmful interference could be severely hampered and needlessly prolonged due to inability to determine the responsible licensee.

Federal Communications Commission.

Cecilia Sigmund,

Federal Register Liaison Officer.

[FR Doc. 2020–11603 Filed 5–28–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0589, OMB 3060–1149, OMB 1270; FRS 16789]

Information Collections 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 might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.'' 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.

DATES: Written comments and recommendations for the proposed information collection should be submitted on or before June 29, 2020.

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 Nicole Ongele, FCC, via email to *PRA@fcc.gov* and to *Nicole.Ongele@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 Nicole Ongele at (202) 418–2991. 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: 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 Number: 3060–0589.

Title: FCC Remittance Advice Forms, FCC Form 159/159–C, 159–B, 159–E, and 159–W.

Form Number(s): FCC Form 159 Remittance Advice, 159–C Remittance Advice Continuation Sheet, 159–B Remittance Advice Bill for Collection, 159–E Remittance Voucher, and 159–W Interstate Telephone Service Provider Worksheet.

Type of Review: Extension of a currently approved collection.

Respondents: Businesses or other for-profit entities; Individuals or households; Not-for-profit institutions; and State, Local, or Tribal Governments.

Number of Respondent and Responses: 102,405 respondents; 102,405 responses.

Estimated Time per Response: 15 minutes (0.25 hours).

Frequency of Response: On occasion and annual reporting requirements; third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory Authority for this information collection is contained in the Communications Act of 1934, as amended; Section 8 (47 U.S.C. 158) for Application Fees; Section 9 (47 U.S.C. 159) for Regulatory Fees; Section 309(j) for Auction Fees; and the Debt Collection Improvement Act of 1996, Public Law 104–134, Chapter 10, Section 31001.

Total Annual Burden: 25,601 hours.

Total Annual Cost: None.

Nature and Extent of Confidentiality: There is no need for confidentiality, except for personally identifiable information (PII) that individuals may submit on one or more of these forms. FCC Form 159 series instructions include a Privacy Act Statement. Furthermore, while the Commission is not requesting that the respondents submit confidential information to the FCC, respondents may request confidential treatment for information they believe to be confidential under 47 CFR Section 0.459 of the Commission's rules. The Commission has a system of records notice (SORN), FCC/OMD–25, Financial Operations Information System (FOIS), to cover any PII that individuals may submit. The SORN is posted on the FCC Privacy web page at: *https://www.fcc.gov/general/privacy-act-information#systems.* Privacy Impact Assessment (PIA): A PIA is being drafted and posted on the FCC Privacy web page at: *https://www.fcc.gov/general/privacy-act-information#systems.*

Needs and Uses: The FCC supports a series of remittance advice forms and a remittance voucher form that may be submitted in lieu of a remittance advice form when entities or individuals electronically submit a payment. A remittance advice form (or a remittance voucher form in lieu of an advice form) must accompany any payment to the Federal Communications Commission (*e.g.* payments for regulatory fees, application filing fees, auctions, fines, forfeitures, Freedom of Information Act (FOIA) billings, or any other debt due to the FCC. Information is collected on these forms to ensure credit for full payment, to ensure entities and individuals receive any refunds due, to service public inquiries, and to comply with the Debt Collection Improvement Act of 1996. On August 12, 2013, the Commission released a Report and Order (R&O), In the Matter Assessment and Collection of Regulatory Fee for Fiscal Year 2013 and Procedures for Assessment and Collection of Regulatory Fees, MD Docket Nos. 13–140 and 12–201, FCC 13–110. In this R&O, the Commission requires that beginning in FY 2014, all regulatory fee payments be made electronically and that the Commission will no longer mail out initial regulatory fee assessments to CMRS providers.

OMB Control Number: 3060–1149.

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Individuals or households, Business or other for-profit, Not-for-profit institutions, and State, Local, or Tribal government.

Number of Respondents and Responses: 259,600 respondents and 259,600 responses.

Estimated Time per Response: .166 hours (10 minutes).

Frequency of Response: One-time reporting requirement.

Obligation to Respond: Voluntary.

Total Annual Burden: 43,267 hours.

Total Annual Cost: No Cost.

Nature and Extent of Confidentiality: Responses to feedback instruments will be confidential.

Privacy Act Impact Assessment: There is no Privacy Act impact as personally identifiable information(PII) will not be collected.

Needs and Uses: The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or change in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management. Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods of assessing potential nonresponse bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

OMB Control Number: 3060–1270.

Title: Protecting National Security Through FCC Programs.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents and Responses: 2,257 respondents; 2,257 responses.

Estimated Time per Response: 3 hours.

Frequency of Response: One-time reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 1.4(b)(1), 1.103(a), 151–154, 201(b), 229, 254, and 1004.

Total Annual Burden: 6,771 hours.

Total Annual Cost: No Cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: The Commission will consider the potential confidentiality of any information submitted, particularly where public release of such information could raise security concerns (*e.g.,* granular location information). We expect, however, that the public interest in knowing whether a carrier uses or owns equipment or services from Huawei or ZTE would significantly outweigh any interest the carrier would have in keeping such information confidential. Respondents may request materials or information submitted to the Commission or to the Universal Service Administrative Company be withheld from public inspection under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: The Commission will submit this information collection to the Office of Management and Budget (OMB) as an extension during this comment period to obtain the full three-year clearance from OMB. Under this information collection, the Commission proposes to collect information to determine the extent to which potentially prohibited equipment exists in current networks and the costs associated with removing such equipment and replacing it with equivalent equipment. The Communications Act of 1934, as amended, requires the ''preservation and advancement of universal service.'' 47 U.S.C. 254(b). The information collection requirements reported under this collection are the result of Commission actions to promote the Act's universal service goals. On November 22, 2019, the Commission adopted a Report and Order, Further Notice of Proposed Rulemaking, and Order, WC Docket No. 18–89, FCC 19–121 (*Protecting Against National Security Threats to the Communications Supply Chain Through FCC Programs*). The *Report and Order* prohibits future use of Universal Service Fund (USF) monies to purchase, maintain, improve, modify, obtain, or otherwise support any equipment or services produced or provided by a company that poses a national security threat to the integrity of communications networks or the communications supply chain. It also initially designated two entities—Huawei Technologies Company (Huawei) and ZTE Corporation (ZTE), along with their affiliates, subsidiaries, and parents—as covered companies posing such a national security threat. In the *Further Notice,* the Commission proposed to make the requirement to remove covered equipment and services from carriers' networks contingent on the availability of a funded reimbursement program, in an effort to mitigate the impact on affected entities. This information collection is designed to collect data from eligible telecommunication carriers (ETCs) and other carriers to determine the extent of which potentially prohibited equipment exists in current networks and the costs associated with removing such equipment and replacing it with equivalent equipment. The data will aid the Commission's review of the record and guide our next steps in this proceeding.

Federal Communications Commission.

Cecilia Sigmund,

Federal Register Liaison Officer.

[FR Doc. 2020–11602 Filed 5–28–20; 8:45 am]

BILLING CODE 6712–01–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–00XX; Docket No. 2020–0001; Sequence No. 2]

Information Collection; Technology Transformation Services—Candidate Experience Surveys

AGENCY: Technology Transformation Services (TTS), Federal Acquisition Service (FAS), General Services Administration (GSA).

ACTION: Notice of request for comments regarding a new information collection.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve a new information collection requirement regarding sending candidate surveys to all applicants who apply to jobs within the Technology Transformation Services (TTS).

DATES: Submit comments on or before July 28, 2020.

ADDRESSES: Submit comments identified by Information Collection 3090–00xx; Technology Transformation Services—Candidate Experience Surveys, by any of the following methods:

Regulations.gov: http://www.regulations.gov. Submit comments via the Federal eRulemaking portal by searching for the OMB Control number 3090–00xx. Select the link ''Comment Now'' that corresponds with ''Information Collection 3090–00xx; Technology Transformation Services—Candidate Experience Surveys''. Follow the instructions on the screen. Please include your name, company name (if any), and ''Information Collection 3090–00xx; Technology Transformation Services—Candidate Experience Surveys'' on your attached document. If your comment cannot be submitted using *https://www.regulations.gov,* call or email the points of contact in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Instructions: Please submit comments only and cite Information Collection 3090–00xx; subject, in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two-to-three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Jennifer Moran, Technology Transformation Services, via email to *jennifer.moran@gsa.gov,* or via phone 202–213–1262.

SUPPLEMENTARY INFORMATION:

A. Purpose

The goal of TTS is to modernize the way the government uses technology by applying modern methodologies and technologies to improve the public's experience with government. In order to accomplish this, we need to be able to attract top technical talent from across the country. This often means competing for talent with the private sector, where companies can often offer more robust compensation and benefits.

In order to remain competitive, it is vital that we provide an exceptional candidate experience and maintain a strong brand reputation. Some of the ways we strive to do this is through providing clear job descriptions, thorough interview preparation and personalized candidate experience throughout the process. In doing so, we are better able to recruit more candidates into doing a tour of duty in the government. Candidate Surveys are a way for us to continuously measure how we are doing and make any necessary improvements to our hiring process so we can continue to hire and attract the top talent we need at the rate we need them in this demanding market.

By consistently asking applicants and candidates for their feedback and reviewing the survey results, we can pinpoint what areas in our process need to be modified, changed, removed, and/or added. Surveys allow respondents to remain anonymous and will be sent out three times during the hiring process:

- After a candidate applies to a role. Data at this stage will help us understand if our job descriptions provide a clear understanding of the roles and responsibilities that we are hiring for. It will also help us understand if our website has thorough enough information about the overall hiring process or if there are more resources that we can be providing.
- After a candidate interviews. Data at this stage will help us understand if we are properly preparing candidates and interviewers for interviews.
- When the candidate is Selected or Not Selected after the Interview. Data at this stage will help us understand what the candidate's experience was with their TTS recruiter overall and if there is anything they think we can improve upon.

B. Annual Reporting Burden

Respondents: 7,400.
Responses per Respondent: 1–3.
Total annual responses: 1,110.
Hours per Response: 5 minutes per survey.
Total Burden Hours: 15 minutes for candidates who complete all 3 surveys.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary, whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW, Washington, DC 20405. ATTN: Information Collection 3090–00xx; Technology Transformation Services—Candidate Experience Surveys. Please cite OMB Control No. 3090–00xx, Technology Transformation Services—Candidate Experience Surveys, in all correspondence.

Beth Anne Killoran,
Deputy Chief Information Officer.

[FR Doc. 2020–11577 Filed 5–28–20; 8:45 am]
BILLING CODE 6820–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2020–0060]

CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHACHSPT) Meeting

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Federal Advisory Committee Act, the CDC and the Health Resources and Services Administration (HRSA), announces the following meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHACHSPT). This meeting is open to the public, limited only by audio and web conference lines available, by accessing the (information below). Time will be available for oral public comment. Persons who desire to make an oral statement, may request it at the time of the public comments period on July 21, 2020 at 3:45 p.m., EDT. Written comments received in advance of the meeting will be included in the official record of the meeting.

DATES: The meeting will be held on July 21, 2020, 2:00 p.m. to 4:00 p.m., EDT.

Written comments must be received on or before July 14, 2020.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2020–0060 by any of the following methods. CDC does not accept; comments by email.

- *Federal eRulemaking Portal: https://www.reulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Staci Morris, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS E–07, Atlanta, Georgia 30329–4027, Attn: CHACHSPT Meeting.

Instructions: All submissions received must include the Agency name and Docket number [CDC–2020–0060]. All relevant comments received in

conformance with the *https://www.regulations.gov* suitability policy will be posted without change to *https://www.regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *https://www.regulations.gov.* Written comments received in advance of the meeting will be included in the official record of the meeting.

Meeting information: The teleconference access is 1–877–603–4228, and the passcode is 42598858. The web conference access is *https://adobeconnect.cdc.gov/chac/.*

FOR FURTHER INFORMATION CONTACT: Staci Morris, Public Health Advisor, CDC, 1600 Clifton Road NE, Mailstop E0–7, Atlanta, Georgia 30329–4027, Telephone (404) 718–7479, Email *SMorris4@cdc.gov.*

SUPPLEMENTARY INFORMATION: *Purpose:* This committee is charged with advising the Director, CDC and the Administrator, HRSA, regarding activities related to prevention and control of HIV/AIDS, Viral Hepatitis and other STDs, the support of health care services to persons living with HIV/AIDS, and education of health professionals and the public about HIV/AIDS, Viral Hepatitis and other STDs.

Public Participation

Written Public Comment: The public is welcome to submit written comments in advance of the meeting. Comments should be submitted in writing by mail according to the instructions provided. The deadline for receipt of written public comment is July 14, 2020. All requests must contain the name, address, and organizational affiliation of the speaker, as well as the topic being addressed. Written comments received in advance of the meeting will be included in the official record of the meeting. Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure.

Matters To Be Considered: The agenda will include updates on recent HRSA and CDC activities involving HIV, STD, and viral hepatitis prevention and treatment and related COVID–19 response activities, as well as discussions on issues related to youth and the President's Initiative on ''Ending the HIV Epidemic: A Plan for America.'' Agenda items are subject to change as priorities dictate.

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. 2020–11496 Filed 5–28–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–20–1185]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Youth Outreach Generic Clearance for the National Center for Health Statistics (NCHS) (OMB Control No. 0920–1185), to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on February 25, 2020 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. 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. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Youth Outreach Generic Clearance for the National Center for Health Statistics (NCHS) (OMB Control No. 0920–1185, Exp. 05/31/2020)—Extension—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

NCHS is authorized to collect data under Section 306 of the Public Health Service Act (42 U.S.C. 242k). NCHS has a history of reaching out to young people to encourage their interest in Science, Technology, Engineering and Math (STEM). Examples of past involvement include adopting local schools, speaking at local colleges, conducting a Statistics Day for high school students, and, most recently, conducting the NCHS Data Detectives Camp for middle school students.

The success of these programs has inspired NCHS leadership and staff to want to look for new and continuing opportunities to positively impact the lives of young people and expand their interest, understanding of, and involvement in the sciences. NCHS requests approval for an Extension of a Generic Clearance mechanism to collect information for these youth outreach activities and to inform future NCHS planning activities. These activities include; hosting the Data Detectives Camp annually; hosting Statistics Day annually; creating youth poster sessions for professional conferences (such as the NCHS National Conference on Health

Statistics or the American Statistical Association Conference etc.); hosting a statistical or health sciences fair or other STEM related competitions; organizing a STEM Career Day or similar activity; developing web-based sites or materials with youth focus as well as other programs developed to meet future youth outreach needs, particularly activities that encourage STEM.

Information will be collected using a combination of methodologies appropriate to each program. These may include: Registration forms, letters of recommendation, evaluation forms; mail surveys; focus groups; automated and electronic technology (*e.g.* email, Web-based surveys); and telephone surveys. OMB approval is requested for three years to conduct the Youth Outreach Generic Clearance for the National Center for Health Statistics (NCHS). Participation is voluntary and there are no costs to respondents other than their time. The total estimated annualized burden hours are 1,750.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of survey	Respondent	Number of respondents	Number of responses/ respondent	Average burden/ response (in hours)
Questionnaires/Applications	Student/Youth	800	1	30/60
Applicants Questionnaire/Application	Parents/Guardians of Applicants	800	1	30/60
Applications, Recommendations, and Other applicant-supporting documentation.	School Officials/Community Representatives	1200	1	30/60
Focus Groups	Student/Youth; Parent/Guardian; School Officials; Other.	50	1	60/60
Other Program Surveys	Student/Youth; Parent/Guardian; School Officials; Other.	600	1	30/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2020–11543 Filed 5–28–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10110, CMS–10156, CMS–10728, and CMS–R–21]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by July 28, 2020.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10110 Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals

CMS–10156 Retiree Drug Subsidy (RDS) Application and Instructions

CMS–10728 Value in Opioid Use Disorder Treatment Demonstration

CMS–R–21 Withholding Medicare Payments to Recover Medicaid Overpayments and Supporting Regulations in 42 CFR 447.31

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a

60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Manufacturer Submission of Average Sales Price (ASP) Data for Medicare Part B Drugs and Biologicals; *Use:* Section 1847A of the Act requires that the Medicare Part B payment amounts for covered drugs and biologicals not paid on a cost or prospective payment basis be based upon manufacturers' average sales price data submitted quarterly to the Centers for Medicare & Medicaid Services (CMS). The reporting requirements are specified in 42 CFR part 414 Subpart J.

The Division of Ambulatory Services (DAS), will utilize the ASP data (ASP and number of units sold as specific in section 1847A of the Act) to determine the Medicare Part B drug payment amounts for CY 2005 and beyond. The manufacturers submit their ASP data for all of their NDCs for Part B drugs. DAS compiles the data, analyzes the data and runs the data through software to calculate the volume-weighted ASP for all of the NDCs that are grouped within a given HCPCS code. The formula to calculate the volume-weighted ASP is the Sum (ASP * units) for all NDCs/Sum (units * bill units per pkg) for all NDCs. DAS provides ASP payment amounts for several components within CMS that utilize 1847(A) payment methodologies to implement various payment policies including, but not limited to, ESRD, OPPS, OTP and payment models. The Department of Health and Human Services' Office of the Inspector General also uses the ASP data in conducting statutorily mandated studies. *Form Number:* CMS–10110 (OMB control number: 0938–0921); *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 300; *Total Annual Responses:* 1,200; *Total Annual Hours:* 15,600. (For policy questions regarding this collection contact Felicia Eggleston at 410 786–9287.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Retiree Drug Subsidy (RDS) Application and Instructions; *Use:* Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and implementing regulations at 42 CFR part 423 subpart R plan sponsors (*e.g.,* employers, unions) who offer prescription drug coverage to their qualified covered retirees are eligible to receive a 28% subsidy for allowable drug costs. In order to qualify, plan sponsors must submit a complete application to the Centers for Medicare & Medicaid Services (CMS) with a list of retirees for whom it intends to collect the subsidy. Once CMS reviews and analyzes the information on the application and the retiree list, notification will be sent to the plan sponsor about its eligibility to participate in the Retiree Drug Subsidy (RDS) Program.

CMS has contracted with an outside vendor to assist in the administration of the RDS program; this effort is called the RDS Center. Plan Sponsors will apply on-line for the retiree drug subsidy by logging on to the RDS Secure website. 42 CFR 423.844 describes the requirement for qualified retiree prescription drug plans who want to receive the retiree drug subsidy. Once the Plan Sponsor submits the RDS application via the RDS Secure website (and a valid initial retiree list) CMS, through the use of its contractor, will analyze the application to determine whether the Plan Sponsor qualifies for the RDS. To qualify for the subsidy, the Plan Sponsor must show that its coverage is as generous as, or more generous than, the defined standard coverage under the Medicare Part D prescription drug benefit. *Form Number:* CMS–10156 (OMB control number: 0938–0957); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits, Not-for-profits institutions; *Number of Respondents:* 1,803; *Total Annual Responses:* 1,803; *Total Annual Hours:* 115,392. (For policy questions regarding this collection contact Ivan Iveljic at 410–786–3312.)

3. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Value in Opioid Use Disorder Treatment Demonstration; *Use:* Value in Opioid Use Disorder Treatment (Value in Treatment) is a 4-year demonstration program authorized under section 1866F of the Social Security Act (Act), which was added by section 6042 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act). The purpose of Value in Treatment, as stated in the statute, is to ''increase access of applicable beneficiaries to opioid use disorder treatment services, improve physical and mental health outcomes for such beneficiaries, and to the extent possible, reduce Medicare program expenditures.'' As required by statute, Value in Treatment will be implemented no later than January 1, 2021.

Section 1866F(c)(1)(A)(ii) specifies that individuals and entities must apply for and be selected to participate in the Value in Treatment demonstration pursuant to an application and selection process established by the Secretary.

Section 1866F(c)(2)(B)(iii) specifies that in order to receive CMF and performance-based incentive payments under the Value in Treatment program, each participant shall report data necessary to: monitor and evaluate the Value in Treatment program; determine if criteria are met; and determine the performance-based incentive payment. *Form Number:* CMS–10728 (OMB control number: 0938–New); *Frequency:* Yearly; *Affected Public:* Individuals and Households; *Number of Respondents:* 12,096; *Total Annual Responses:* 12,096; *Total Annual Hours:* 1,285. (For policy questions regarding this collection contact Rebecca VanAmburg at 410–786–0524.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Withholding Medicare Payments to Recover Medicaid Overpayments and Supporting Regulations in 42 CFR 447.31; *Use:* Certain Medicaid providers that are subject to offsets for the collection of Medicaid overpayments may terminate or substantially reduce their participation in Medicaid, leaving the state Medicaid agency unable to recover the amounts due. Recovery procedures allow for determining the amount of overpayments and offsetting the overpayments by withholding the provider's Medicare payments. To effectuate the withholding, the state agency must provide their respective CMS regional office with certain documentation that identifies the provider and the Medicaid overpayment amount. The agency must also demonstrate that the provider was notified of the overpayment and that demand for the overpayment was made. An opportunity to appeal the overpayment determination must be afforded to the provider by the Medicaid state agency. Lastly, Medicaid state agencies must notify CMS when to terminate the withholding; *Form Number:* CMS–R–21 (OMB control number: 0938–0287); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 54; *Total Annual*

Responses: 27; *Total Annual Hours:* 81. (For policy questions regarding this collection contact Stuart Goldstein at 410–786–0694.)

Dated: May 21, 2020.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020–11387 Filed 5–28–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10185]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *June 29, 2020.*

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

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.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

1. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

2. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* Medicare Part D Reporting Requirements; *Use:* Data collected via Medicare Part D Reporting Requirements will be an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries. For all reporting sections, data are reported electronically to CMS. Each reporting section is reported at one of the following levels: Contract (data should be entered at the H#, S#, R#, or E# level) or Plan (data should be entered at the Plan Benefit Package (PBP level, *e.g.,* Plan 001 for contract H#, R#, S#, or E). Sponsors should retain documentation and data records related to their data submissions. Data will be validated, analyzed, and utilized for trend reporting by the Division of Clinical and Operational Performance (DCOP) within the Medicare Drug Benefit and C & D Data Group. If outliers or other data anomalies are detected, DCOP will work in collaboration with other Divisions within CMS for follow-up and resolution.

In accordance with Title I, Part 423, Subpart K (§ 423.514), the Act requires each Part D Sponsor to have an effective procedure to provide statistics indicating:

- The cost of its operations
- the patterns of utilization of its services
- the availability, accessibility, and acceptability of its services
- information demonstrating it has a fiscally sound operation
- other matters as required by CMS

Subsection 423.505 of the MMA regulation establishes as a contract provision that Part D Sponsors must comply with the reporting requirements for submitting drug claims and related information to CMS. *Form Number:* CMS–10185 (OMB control number: 0938–0992); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 744; *Total Annual Responses:* 17,080; *Total Annual Hours:* 25,256. (For policy questions regarding this collection contact Chanelle Jones at 410–786–8008.)

Dated: May 22, 2020.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020–11424 Filed 5–28–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10537]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by June 29, 2020.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *OR* Email: *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

1. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

2. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision with change of a currently approved collection; *Title of Information Collection:* National Implementation of Hospice Experience of Care Survey (CAHPS Hospice Survey); *Use:* CMS launched the development of the CAHPS® Hospice Survey in 2012. Public reporting of the results on Hospice Compare started in 2018. The goal of the survey is to measure the experiences of patients and their caregivers with hospice care. The survey was developed to:

- Provide a source of information from which selected measures could be publicly reported to beneficiaries and their family members as a decision aid for selection of a hospice program;
- Aid hospices with their internal quality improvement efforts and external benchmarking with other facilities; and
- Provide CMS with information for monitoring the care provided.

CAHPS is a standardized family of surveys developed by the Agency for Healthcare Research and Quality (AHRQ) for patients to assess and report the quality of care they receive from their health care providers and health care delivery systems.

CMS announced its intention to implement the CAHPS® Hospice Survey in the FY 2014 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements; and Updates on Payment Reform. National implementation of the survey launched on January 1, 2015 with hospices administering the survey for a ''dry run'' for at least one month in the first quarter of 2015. Starting April 1, 2015 (second quarter), hospices were required to participate on a monthly basis in order to receive the full Annual Payment Update (APU). Implementation is ongoing and there have been no changes to the questionnaire.

Publicly reporting comparative survey results related to patients' perspectives of the care they receive from providers and plans collected through the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Surveys support CMS's efforts to put patients first and improve the beneficiary experience. *Form Number:* CMS–10537 (OMB control number: 0938–1257); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 1,032,004; *Total Annual Responses:* 1,032,004; *Total Annual Hours:* 180,004.

(For policy questions regarding this collection contact Debra Dean-Whittaker at 410–786–0848.)

Dated: May 21, 2020.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020–11389 Filed 5–28–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Federal Case Registry (FCR) (OMB #0970–0421)

AGENCY: Office of Child Support Enforcement, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the Federal Case Registry (FCR). There are no changes to the collection instruments used for the FCR (current Office of Management and Budget (OMB) approval expires January 31, 2021).

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *infocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation (OPRE), 330 C Street SW, Washington, DC 20201, Attn: ACF

Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: ACF implemented the FCR within the Federal Parent Locator Service (FPLS) on October 1, 1998, pursuant to federal law. The FCR is a national database of information pertaining to child support cases processed by state child support agencies, referred to as ''IV–D'' cases, and non-IV–D support orders privately established or modified by courts or tribunals on or after October 1, 1998. FCR information is submitted by each State Case Registry (SCR), which is a central registry of child support orders and cases. The FCR automatically compares new SCR submissions to existing FCR information and notifies state agencies if an IV–D case participant in the state appears as a participant in an IV–D or non-IV–D case in another state.

Respondents: State child support enforcement agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
Appendix G: Input Record Layout	54	151	0.0333	272

Estimated Total Annual Burden Hours: 272.

Comments: The Department specifically requests comments 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) the quality, utility, and clarity of the information to be collected; 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: The information collection activities pertaining to the FCR are authorized by: 42 U.S.C. 653(h), which requires the establishment of the FCR within the FPLS; 42 U.S.C. 654a(e), which requires state child support agencies to include a SCR in the state's automated system; and 42 U.S.C. 654a(f)(1), which requires states to conduct information comparison activities between the SCR and the FCR.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–11578 Filed 5–28–20; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–5364]

Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised); Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised guidance for industry entitled ''Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised).'' This is a revision to the first edition of this final guidance, which issued in March 2020, and is intended to assist those required to submit cigarette plans for cigarette packages and cigarette advertisements by providing content, timing, and other recommendations related to those submissions. FDA is revising this guidance to reflect the May 8, 2020, court order that postponed, by 120 days, the effective date of the final rule, entitled ''Tobacco Products; Required Warnings for Cigarette Packages and Advertisements.'' Pursuant to the court order, this revised guidance strongly encourages entities to submit cigarette plans to FDA as soon as possible after publication of the final rule, and in any event within 5 months and 120 days after the date of publication of the final rule (*i.e.,* by December 16, 2020).

DATES: The announcement of the revised guidance is published in the **Federal Register** on May 29, 2020.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–D–5364 for ''Submission of Plans

for Cigarette Packages and Cigarette Advertisements (Revised).'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff office between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Lauren Belcher or Courtney Smith, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, email: *AskCTPRegulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised guidance for industry entitled ''Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised).''

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) was enacted on June 22, 2009, and granted FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products. The Tobacco Control Act also amended section 4 of the Federal Cigarette Labeling and Advertising Act (FCLAA) to direct FDA to issue regulations requiring each cigarette package and advertisement to bear a new textual warning label statement accompanied by color graphics depicting the negative health consequences of smoking (section 201 of the Tobacco Control Act). In enacting this legislation, Congress also provided that FDA may adjust the required warnings if FDA found that such a change would promote greater public understanding of the risks associated with the use of tobacco products (section 202 of the Tobacco Control Act). The Tobacco Control Act also modified the requirements of the FCLAA regarding the submission of cigarette plans for the random and equal display and distribution of required warnings on cigarette packages and quarterly rotation of required warnings in cigarette advertisements. It also requires that such cigarette plans be submitted to FDA for review and approval, rather than to the Federal Trade Commission.

In the **Federal Register** of March 18, 2020, FDA issued a rule entitled ''Tobacco Products; Required Warnings for Cigarette Packages and Advertisements'' (85 FR 15638). The rule specifies the color graphics that must accompany the new textual warning label statements and establishes marketing requirements for cigarette packages and advertisements. The marketing requirements include, among other things, submission of a cigarette plan that provides for the random and equal display and distribution of the required warnings on cigarette packages and quarterly rotation of the required warnings in cigarette advertisements, as described under section 4 of FCLAA.

On April 3, 2020, the final rule was challenged in the U.S. District Court for the Eastern District of Texas.[1] Due to the COVID–19 pandemic and its impacts, on May 8, 2020, the court granted a joint motion to govern proceedings in that case and postpone the effective date of the final rule by 120 days.[2] The new effective date of the final rule is October 16, 2021. Pursuant to the court order, any obligation to comply with a deadline tied to the effective date of the rule is similarly postponed, and those obligations and deadlines are now tied to the postponed effective date. As such, this revised guidance strongly encourages entities to submit cigarette plans to FDA as soon as possible after publication of the final rule, and in any event within 5 months and 120 days after the date of publication of the final rule (*i.e.,* by December 16, 2020).

II. Significance of Guidance

FDA is issuing this guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA regarding the submission of plans for cigarette packages and cigarette advertisements. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR 1141.10 have been approved under 0910–0877.

IV. Electronic Access

Persons with access to the internet may obtain an electronic version of the guidance at either *https://www.regulations.gov* or *https://www.fda.gov/TobaccoProducts/*

[1] *R.J. Reynolds Tobacco Co. et al.* v. *United States Food and Drug Administration et al.,* No. 6:20–cv–00176 (E.D. Tex. filed April 3, 2020).

[2] *R.J. Reynolds Tobacco Co. et al.,* No. 6:20–cv–00176 (E.D. Tex. May 8, 2020) (order granting joint motion and establishing schedule), Doc. No. 33.

GuidanceComplianceRegulatory Information/default.htm.

Dated: May 22, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–11463 Filed 5–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: Delta States Rural Development Network Grant Program, OMB No. 0915–0386—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this Notice has closed.

DATES: Comments on this ICR should be received no later than June 29, 2020.

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 a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Delta States Rural Development Network Grant Program, OMB No. 0915–0386—Extension.

Abstract: The Delta States Rural Development Network Grant (Delta) Program is authorized by the Public Health Service Act, Section 330A(e) (42 U.S.C. 254c(e)), as Public Law 114–53. The Delta Program supports projects that demonstrate evidence-based and/or promising approaches around cardiovascular disease, diabetes, acute ischemic stroke, or obesity to improve health status in rural communities throughout the Delta Region. Key features of projects are adoption of an evidence-based approach, demonstration of health outcomes, program replicability, and sustainability.

A 60-day notice published in the **Federal Register** on August 27, 2019, vol. 84, No. 166; pp. 44902–03. There were no public comments.

Need and Proposed Use of the Information: For this program, performance measures were drafted to provide data useful to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993 (Pub. L. 103–62). These measures cover the principal topic areas of interest to the Federal Office of Rural Health Policy (FORHP) including the following: (a) Access to care, (b) population demographics, (c) staffing, (d) sustainability, (e) project specific domains, and (f) health related clinical measures. These measures speak to FORHP's progress toward meeting the goals set.

Likely Respondents: The respondents are the recipients of the Delta States Rural Development Network Program.

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
Delta States Rural Development Network Program Performance Improvement Measurement System	12	1	12	1.66	20
Total	12		12		20

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–11571 Filed 5–28–20; 8:45 am]

BILLING CODE 4165–15–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; Joint Degeneration and Aging.

Date: July 17, 2020.

Time: 9:00 a.m. to 12:30 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: Joshua Jin-Hyouk Park, 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) 496–6208, *joshua.park4@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: May 22, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11500 Filed 5–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; 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 Minority Health and Health Disparities Special Emphasis Panel; NIMHD Career Development Award Review Panel.

Date: July 8–9, 2020.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Gateway Plaza, 7201 Wisconsin Avenue, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Richard C. Palmer, DrPH, Health Scientist Administrator, National Institute on Minority Health and Health Disparities, National Institutes of Health, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 451–2432, *richard.palmer@nih.gov.*

Dated: May 26, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11624 Filed 5–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Eye Institute Special Emphasis Panel; NEI Genetics/Genomics Applications

Date: June 23, 2020.

Time: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Eye Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3400, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Brian Hoshaw, Ph.D., Designated Federal Official, Division of Extramural Research, National Eye Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3400, Rockville, MD 20817, 301–451–2020, *hoshawb@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: May 26, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11621 Filed 5–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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 of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK Exploratory Centers (P20) and Interaction Core (U24) for Benign Urology.

Date: June 25, 2020.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Blvd., Bethesda, MD 20892 (Video Meeting).

Contact Person: Tian, Lan, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, 6707 Democracy Boulevard, Suite 7016, Bethesda, MD 20892–5452, (301) 496–7050, *tianl@niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: May 22, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11501 Filed 5–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of The Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Office of AIDS Research Advisory Council.

The meeting will be open to the public via NIH videocast. The URL link to this meeting is: *https://videocast.nih.gov/watch=37775.* Individuals who plan to attend the virtual meeting 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.

Name of Committee: Office of AIDS Research Advisory Council.

Date: June 25, 2020.

Time: 12:30 p.m. to 4:15 p.m.

Agenda: OAR Director's Report; updates from the DHHS HIV/AIDS Treatment and Prevention Guidelines; Discussion regarding research opportunities and priorities for COVID19 and HIV; discussion with OARAC members regarding the impact of the pandemic and Research Recovery Planning and Efforts at their institutions; and public comment.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892, (Virtual Meeting).

Contact Person: Mary T. Glenshaw, Ph.D., MPH, Senior Science Advisor, OD/DPCPSI/OAR, 5601 Fishers Lane, Room 2E40, Rockville, MD 20850, *mary.glenshaw@nih.gov*.

Any interested person may file written comments within 15 days before the meeting with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, email 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.oar.nih.gov,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: May 22, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11554 Filed 5–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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 of General Medical Sciences Special Emphasis Panel; Review of Centers of Biomedical Research Excellence (COBRE) P20 Applications.

Date: July 16–17, 2020.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Nina Sidorova, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institutes of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18, Bethesda, MD 20814, (301) 402–2783, *sidorova@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: May 22, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11503 Filed 5–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; 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 of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA–DK19–024: HIRN–CBDS–Discovery of Early Type 1 Diabetes Disease Processes in the Human Pancreas.

Date: July 9, 2020.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy II, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Najma S. Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7349, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8894, *begumn@niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: May 22, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11502 Filed 5–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as

amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Neurological Sciences Training Initial Review Group; NST–1 Subcommittee 2020/10 NST–1 Study Section.

Date: June 1–2, 2020.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Neuroscience Center, 6001 Executive Blvd., North Bethesda, MD 20852 (Video Assisted Meeting).

Contact Person: William C. Benzing, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS, NIH NSC, 6001 Executive Blvd., Suite 3204, MSC 9529, Bethesda, MD 20892–9529, (301) 496–0660, *benzingw@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Review of DSPAN F99/K00 Applications.

Date: June 3, 2020.

Time: 7:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Neuroscience Center, 6001 Executive Blvd., North Bethesda, MD 20852 (Video Assisted Meeting).

Contact Person: William C. Benzing, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS, NIH, NSC, 6001 Executive Blvd., Suite 3204, MSC 9529, Bethesda, MD 20892–9529, (301) 496–0660, *benzingw@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Neurological Sciences Training Initial Review Group; NST–2 Subcommittee NST–2 Subcommittee.

Date: June 4–5, 2020.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: Neuroscience Center, 6001 Executive Blvd., North Bethesda, MD 20852 (Video Assisted Meeting).

Contact Person: Deanna Lynn Adkins, Ph.D., Scientific Review Officer, Scientific Review Branch, NSC Building, Bethesda, MD 20892, 301–496–9223, *deanna.adkins@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Fellowship Review.

Date: June 8, 2020.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Neuroscience Center, 6001 Executive Blvd., North Bethesda, MD 20852 (Video Assisted Meeting).

Contact Person: Deanna Lynn Adkins, Ph.D., Scientific Review Officer, Scientific Review Branch, NSC Building, Bethesda, MD 20892, 301–496–9223, *deanna.adkins@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Blueprint ENDURE R25 Review.

Date: June 9, 2020.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Neuroscience Center, 6001 Executive Blvd., North Bethesda, MD 20852 (Video Assisted Meeting).

Contact Person: Delany Torres, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS Neuroscience Center Building (NSC), 6001 Executive Blvd., Suite 3208, Bethesda, MD 20892, *delany.torressalazar@nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: May 22, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11514 Filed 5–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel; Member Conflict: Community Level Health Promotion and Behavior and Implementation Research. June 17, 2020, 09:00 a.m. to June 17, 2020, 06:00 p.m., National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on May 12, 2020, 85 FR 28018.

The meeting format is being updated to a Video Assistant Meeting. Meeting dates and time remain the same. The meeting is closed to the public.

Dated: May 26, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11622 Filed 5–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Division of Intramural Research Board of Scientific Counselors, National Institute of Allergy and Infectious Diseases.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Division of Intramural Research Board of Scientific Counselors, National Institute of Allergy and Infectious Diseases.

Date: June 15–17, 2020.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 50 Center Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Laurie Lewellan, Board of Scientific Counselors, Committee Manager, Division of Intramural Research Program Support Staff, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Building 33, Room 1N24, 33 North Drive, Bethesda, MD 20892, *Laurie.Lewallen@nih.gov*, 301–761–6362.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology,

and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: May 22, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11555 Filed 5–28–20; 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 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 Heart, Lung, and Blood Institute Special Emphasis Panel; HEAL Initiative: Reversal of Opioid-Induced Ventilatory Depression.

Date: June 23, 2020.

Time: 9:00 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: NIH/NHLBI, 6705 Rockledge Drive, Bethesda, MD 20814 (Telephone Conference Call).

Contact Person: Michael P. Reilly, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 208–Z, Bethesda, MD 20892, (301) 827–7975, *reillymp@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: May 26, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11623 Filed 5–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel Blueprint Neurotherapeutics Network (BPN): Small Molecule Drug Discovery and Development for Disorders of the Nervous System.

Date: June 12, 2020.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Neuroscience Center, 6001 Executive Blvd., North Bethesda, MD 20852, (Video Assisted Meeting).

Contact Person: Joel A Saydoff, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, NSC, 6001 Executive Blvd., Room 3205, MSC 9529, Bethesda, MD 20892, (301) 496–9223, *joel.saydoff@nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel BRAIN Initiative: Research Resource Grants for Technology Integration and Dissemination (U24 Clinical Trial Not Allowed).

Date: June 12, 2020.

Time: 10:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Neuroscience Center, 6001 Executive Blvd., North Bethesda, MD 20852, (Video Assisted Meeting).

Contact Person: Bo-Shiun Chen, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, Nsc, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892, (301) 496–9223, *bo-shiun.chen@nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel NST–1 Member Conflict SEP.

Date: June 15, 2020.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852, (Virtual Meeting).

Contact Person: William C. Benzing, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS, NIH, NSC, 6001 Executive Blvd., Suite 3204, MSC 9529, Bethesda, MD 20892–9529, (301) 496–0660, *benzingw@mail.nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel Translational Neural, Brain, and Pain Relief Devices.

Date: June 16–17, 2020.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Neuroscience Center, 6001 Executive Blvd., North Bethesda, MD 20852, (Video Assisted Meeting).

Contact Person: Diana M Cummings, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Neurological Disorders and Stroke, NIH, NSC, 6001 Executive Blvd., Suite 3208, Bethesda, MD 20892, *cummingsdi@ninds.nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel Data Harmonization, Curation and Secondary Analysis of Existing Clinical Datasets (R61/R33).

Date: June 18, 2020.

Time: 11:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Neuroscience Center, 6001 Executive Blvd., North Bethesda, MD 20852, (Video Assisted Meeting).

Contact Person: Marilyn Moore-Hoon, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, National Institute of Neurological Disorders and Stroke, Bethesda, MD 20892, (301) 827–9087, *mooremar@mail.nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke Initial Review Group Neurological Sciences and Disorders A.

Date: June 22–23, 2020.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Neuroscience Center, 6001 Executive Blvd., North Bethesda, MD 20852, (Video Assisted Meeting).

Contact Person: Natalia Strunnikova, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892, (301) 402–0288, *natalia.strunnikova@nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke Initial Review Group Neurological Sciences and Disorders B.

Date: June 25–26, 2020.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Neuroscience Center, 6001 Executive Blvd., North Bethesda, MD 20852, (Video Assisted Meeting).

Contact Person: Joel A. Saydoff, Ph.D., Scientific Review Officer, Scientific Review

Branch, Division of Extramural Activities, NINDS/NIH, NSC, 6001 Executive Blvd., Room 3205, MSC 9529, Bethesda, MD 20892, (301) 496–9223, *joel.saydoff@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: May 22, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–11552 Filed 5–28–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2020–0187]

Proposed Distribution of Scheduled Navigation Safety Messages (Broadcast Notices to Mariners) by Mobile and Internet Methods

ACTION: Notice and request for comments.

SUMMARY: The Coast Guard will begin making broadcast notices to mariners containing locally relevant navigation information accessible by mobile devices and the internet. New methods of information delivery will include Rich Site Summary also known as Really Simple Syndication (RSS) feeds, email, and other means such as web-based graphic interfaces. The Coast Guard believes the internet and mobile availability will allow greater numbers of mariners to access this information, and to do so in a more-timely, reliable, convenient, and customized manner. Currently, the only way to obtain this information is to tune in to local Coast Guard broadcasts that take place on very high frequency (VHF) marine radio two or more times per day.

DATES: Comments must be submitted to the online docket via *https://www.regulations.gov* on or before July 28, 2020.

ADDRESSES: You may submit comments identified by docket number USCG–2020–0187 using the Federal e-Rulemaking Portal at *http://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: For information about this document, please call or email Eugene Diotalevi, Coast Guard Navigation Center; telephone: 703–313–5800; email: *BNM@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Public Participation and Comments

We encourage you to submit comments (or related material) on this Notice. We will consider all submissions and may adjust our final action based on your comments. If you submit a comment, please include the docket number for this notice, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov.* If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted, or a final rule is published.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Abbreviations

BNM Broadcast notices to mariners
NAVAREA Navigational Area
NAVTEX Navigation Telex Radio
RSS Rich Site Summary or Really Simple Syndication
VHF Very High Frequency

Discussion

The Coast Guard broadcasts scheduled navigation safety messages on VHF marine radio. These messages, called broadcast notices to mariners (BNMs), provide information about the status of Coast Guard aids-to-navigation (*e.g.* buoys, beacons, and lights), navigational hazards, maritime events, and other locally relevant maritime safety information. Scheduled broadcasts normally occur every six to twelve hours on marine VHF Channel 22A, and typically follow a brief announcement on Channel 16 reminding listeners that a Channel 22A broadcast is about to begin. The Coast Guard makes such broadcasts in order to alert mariners to information that will later be consolidated into local notices to mariners documents, which are published weekly by each Coast Guard District. Local notices to mariners documents are distributed at *https://www.navcen.uscg.gov/LNM.*

The information in BNMs is primarily targeted to local situations and conditions occurring within U.S. ports and waterways and in near-shore, and in-shore waters. These broadcasts should not be confused with other official navigational safety messages transmitted for the benefit of offshore and international maritime vessel traffic through established, internationally coordinated means, such as NAVTEX, NAVAREA, and coastal warnings. The Coast Guard is seeking to make such navigation safety information available to mobile device and internet users, which is expected to offer the following advantages:

(1) *Improved Information Reach.* More boaters and professional mariners for whom the navigation information is relevant will have access to it. The overwhelming majority of current VHF broadcasts concern events, hazards, aids-to-navigation, and other situations that are located in areas where there is offshore mobile data coverage. Greater numbers of mariners, especially those operating close to shore, increasingly make use of mobile technology in lieu of, or in addition to VHF marine radio. This will allow more people to benefit from access to the information.

(2) *Greater Convenience.* The Coast Guard plans to publish the information on an open-facing website that will allow mariners to customize the manner of delivery. For example, mariners will be able to receive an email for each broadcast made in a specified area; may choose to subscribe to an RSS feed; or may choose to visit a mobile-accessible website that displays the broadcasts that apply to a given geographical area. The Coast Guard is also developing other ways to access the information, including graphic interfaces, or through downloadable chart overlays that show the locations where pertinent marine safety information applies. Mariners will be able to access the latest information during times that are convenient to their situation, for example, while they are planning a voyage, or as they approach an entrance to a port or channel.

(3) *Better Timeliness.* Mariners will not have to wait for the next scheduled VHF broadcast to access critical information. They will gain access to

individual navigation messages as soon as they are published.

The proposed new system of information distribution is presently being tested in the Fifth Coast Guard District. The public is urged to examine the following RSS feed as an illustration of this proposed new system at: *https://public.govdelivery.com/topics/USDHSCG_250/feed.rss* or to test out the graphic interface that returns customized reports of the most up-to-date broadcast notices in the Fifth Coast Guard District at *https://navcen.uscg.gov/bnmmessages/DistrictSearchV1.php?d=5&i=4.* This proposed new system of information distribution would not impact those other systems and procedures.

The Coast Guard is interested in the public's views about the proposed new system of information distribution being tested in the Fifth Coast Guard District, including ideas for how best to organize and distribute navigation safety information to mobile device users. The Coast Guard will consider all comments from the public. After considering any comments received, the Coast Guard will issue a notice in the **Federal Register** indicating how the matter will be resolved.

This notice is issued under the authority of 14 U.S.C. 504(a)(16) and 5 U.S.C. 552(a).

Dated: May 26, 2020.

Michael D. Emerson,

Director, Marine Transportation Systems.

[FR Doc. 2020–11619 Filed 5–28–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2020–0189]

Information Collection Request to Office of Management and Budget; OMB Control Number: 1625–0073

AGENCY: Coast Guard, DHS.

ACTION: Sixty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0073, Alteration of Unreasonable Obstructive Bridges; without change.

Our ICR describes the information we seek to collect from the public. Before submitting this ICR to OIRA, the Coast Guard is inviting comments as described below.

DATES: Comments must reach the Coast Guard on or before July 28, 2020.

ADDRESSES: You may submit comments identified by Coast Guard docket number [USCG–2020–0189] to the Coast Guard using the Federal eRulemaking 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.

A copy of the ICR is available through the docket on the internet at *https://www.regulations.gov.* Additionally, copies are available from: Commandant (CG–6P), Attn: Paperwork Reduction Act Manager, U.S. Coast Guard, 2703 Martin Luther King Jr. Ave. SE, STOP 7710, Washington, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, or fax 202–372–8405, for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) The practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. Consistent with the requirements of Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs, and Executive Order 13777, Enforcing the Regulatory Reform Agenda, the Coast Guard is also requesting comments on the extent to which this request for information could be modified to reduce the burden on respondents.

In response to your comments, we may revise this ICR or decide not to seek an extension of approval for the Collection. We will consider all comments and material received during the comment period.

We encourage you to respond to this request by submitting comments and related materials. Comments must contain the OMB Control Number of the ICR and the docket number of this request, [USCG–2020–0189], and must be received by July 28, 2020.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Information Collection Request

Title: Alteration of Unreasonable Obstructive Bridges.

OMB Control Number: 1625–0073.

Summary: The collection of information is a request to determine if the bridge is unreasonably obstructive.

Need: 33 U.S.C. 494, 502, 511, 513, 514, 515 516, 517, 521, 522, 523 and 524 authorize the Coast Guard to require the removal or alteration of bridges and causeways over the navigable waters of the United States and that the Coast Guard deems to be unreasonably obstructive.

Forms: None.

Respondents: Public and Private Owners of bridges over navigable waters of the United States.

Frequency: Occasional.

Hour Burden Estimate: The estimated burden is 160 hours a year.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended.

Dated: May 22, 2020.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2020–11537 Filed 5–28–20; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0030223; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Department of Anthropology, Southern Methodist University, Dallas, TX

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Department of Anthropology, Southern Methodist University has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Department of Anthropology, Southern Methodist University. If no additional requestors come forward, transfer of control of the human remains to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the Department of Anthropology, Southern Methodist University at the address in this notice by June 29, 2020.

ADDRESSES: B. Sunday Eiselt, Department of Anthropology, Southern Methodist University, 3225 Daniel Avenue, Heroy Hall #450, Dallas, TX 75205, telephone (214) 768–2915, email *seiselt@smu.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the Department of Anthropology, Southern Methodist University, Dallas, TX. The human remains were removed from Red River County, TX.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Department of Anthropology, Southern Methodist University professional staff in consultation with representatives of the Apache Tribe of Oklahoma; Caddo Nation of Oklahoma; Coushatta Tribe of Louisiana; Delaware Nation, Oklahoma; The Choctaw Nation of Oklahoma; Tonkawa Tribe of Indians of Oklahoma; and the Wichita and Affiliated Tribes (Wichita, Keechi, Waco, and Tawakonie), Oklahoma (hereafter referred to as ''The Tribes'').

History and Description of the Remains

At an unknown date, human remains representing, at minimum, one individual were removed from Red River County, TX. The human remains of this collection are five skull fragments. The provenience information provided for these fragments are ''Clarksville, Red River County, Texas.'' This appears to be part of Collins' record keeping system, in which he used counties or states to indicate a general area. Since this is the only context, it is not possible to assign an associated time period or culture with these human remains. No known individuals were identified. No associated funerary objects are present.

Determinations Made by the Department of Anthropology, Southern Methodist University

Officials of the Department of Anthropology, Southern Methodist University have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on geographical location.
- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and any present-day Indian Tribe.
- According to final judgments of the Indian Claims Commission or the Court of Federal Claims, the land from which the Native American human remains were removed is the aboriginal land of The Tribes.
- Treaties, Acts of Congress, or Executive Orders, indicate that the land from which the Native American human remains were removed is the aboriginal land of The Tribes.
- Pursuant to 43 CFR 10.11(c)(1), the disposition of the human remains may be to The Tribes.

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to B. Sunday Eiselt, Department of Anthropology, Southern Methodist University, 3225 Daniel Avenue, Heroy Hall #450, Dallas, TX 75205, telephone (214) 768–2915, email *seiselt@smu.edu,* by June 29, 2020. After that date, if no additional requestors have come forward, transfer of control of the human remains to The Tribes may proceed.

The Department of Anthropology, Southern Methodist University is responsible for notifying the Tribes that this notice has been published.

Dated: April 21, 2020.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2020–11566 Filed 5–28–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0030209; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Connecticut State Museum of Natural History, University of Connecticut, Storrs, CT

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Connecticut State Museum of Natural History, University of Connecticut has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian Tribes or Native Hawaiian organizations. Lineal

descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the Connecticut State Museum of Natural History, University of Connecticut. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the Connecticut State Museum of Natural History, University of Connecticut at the address in this notice by June 29, 2020.

ADDRESSES: Dr. Jacqueline Veninger-Robert, NAGPRA Coordinator, University of Connecticut, 354 Mansfield Road, Unit 1176, Storrs, CT 06269–1176, telephone (860) 486–6953, email *jacqueline.veninger@uconn.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the Connecticut State Museum of Natural History, University of Connecticut, Storrs, CT. The human remains and associated funerary objects were removed from the village and burial site of Khustenete, Curry County, OR.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Connecticut State Museum of Natural History, University of Connecticut professional staff in consultation with representatives of the Confederated Tribes of Siletz Indians of Oregon (previously listed as Confederated Tribes of the Siletz Reservation); Confederated Tribes of the Coos, Lower Umpqua and Siuslaw Indians; Confederated Tribes of the Grand Ronde Community of Oregon; Coquille Indian Tribe (previously listed as Coquille Tribe of Oregon); Elk Valley Rancheria, California; and the Tolowa Dee-ni' Nation (previously listed as Smith River Rancheria, California)(hereafter referred to as ''The Consulted Tribes'').

History and Description of the Remains

From 1942–1955, human remains representing, at minimum, 11 individuals were removed from Khustenete, an Athabaskan village and burial site in Curry County, OR (site 35CU157). Khustenete was excavated by physical anthropologist William S. Laughlin and avocational archeologist W.T. Edmundson. At the time of removal, the site was located within the private property of W.W. Ostrander. Today, it is within in the bounds of Samuel H. Broadman State Park.

Laughlin was a professor in the anthropology department at the University of Connecticut (1969–1999). Earlier, he had served on the faculty of the University of Oregon (1949–1955) and the University of Wisconsin (1955–1969). Laughlin's correspondence and journals—archived at the University of Alaska and the University of Oregon—state that analysis of the Khustenete collection, which includes human remains and artifacts not under the control of the University of Connecticut, were examined at Harvard University (where Laughlin received his doctorate in 1949) and the University of Oregon. The 11 individuals and associated funerary objects in this notice were found in Laughlin's home following his death in 2001, and were donated to the Connecticut State Museum of Natural History, University of Connecticut in 2014 by Laughlin's family.

Skeletal analysis of the human remains at the University of Connecticut was undertaken by Doug Owsley in 2015, during a visit to the University. Inventory numbers identifying the individuals are those assigned by Laughlin and Edmundson. Of the 11 individuals identified by Owsley, nine are thought to be female, one is male, and one is of undetermined sex. Age analysis suggests the human remains belong to one child, one adolescent, five young adults, one adult, two older adults, and one of undetermined age. Three of the individuals were conserved with funerary objects. The four associated funerary objects include one lot of pine nut shell beads, one shell, one bone tool, and one decayed wood fragment thought to be cedar wood planking that lined a grave.

Khustenete was initially excavated in 1873 by Paul Schumacher, a member of the USGS survey of the northwest Pacific coast. Schumacher's description of the burials indicates that they were of post-contact date due to the presence of European trade goods. Conversely, Laughlin and Edmundson believed the burials they excavated date to the pre-contact era, although they did not provide more detailed information regarding specific dates or archeological/cultural periods.

While subsequent radiocarbon dating of the site has indicated a late prehistoric/historic period, 450 +/- 70 and 320 +/- 60 RYBP, the samples were taken from a disturbed context. Nonetheless, Khustenete probably was a multi-period occupation site.

Khustenete was excavated intermittently on the property of W. W. Ostrander, from 1942 to 1955. During these excavations, a total of 37 distinguishable burials—but probably more—were documented. Fifteen of those burials were of infants (most of the infant burials were not disinterred). Documentation of the burials and record keeping was not consistent.

Sites along the coasts and river valleys of southwestern Oregon and northwestern California lie within the current and historically documented territory of the Athabaskan peoples of the Pacific Northwest (Neilson 1927; Berreman 1937; Swanton 1952). Historical documents, treaties, geopolitical distribution, geographical location, archeological, anthropological, and biological data, oral histories, and linguistics show that the Khustenete site is ancestral to the Confederated Tribes of Siletz Indians of Oregon (previously listed as Confederated Tribes of the Siletz Reservation); Elk Valley Rancheria, California; and the Tolowa Dee-ni' Nation (previously listed as Smith River Rancheria, California).

Determinations Made by the Connecticut State Museum of Natural History, University of Connecticut

Officials of the Connecticut State Museum of Natural History, University of Connecticut have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 11 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the four objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group

identity that can be reasonably traced between the Native American human remains and associated funerary objects and the Confederated Tribes of Siletz Indians of Oregon (previously listed as Confederated Tribes of the Siletz Reservation); Elk Valley Rancheria, California; and the Tolowa Dee-ni' Nation (previously listed as Smith River Rancheria, California)(hereafter referred to as ''The Tribes'').

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Dr. Jacqueline Veninger-Robert, NAGPRA Coordinator, University of Connecticut, 354 Mansfield Road, Unit 1176, Storrs, CT 06269–1176, telephone (860) 486–6953, email *jacqueline.veninger@uconn.edu,* by June 29, 2020. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to The Tribes may proceed.

The Connecticut State Museum of Natural History, University of Connecticut is responsible for notifying The Consulted Tribes that this notice has been published.

Dated: April 20, 2020.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2020–11561 Filed 5–28–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0030224; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Department of Anthropology, Southern Methodist University, Dallas, TX

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Department of Anthropology, Southern Methodist University has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the Department of Anthropology, Southern Methodist University. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains associated funerary objects should submit a written request with information in support of the request to the Department of Anthropology, Southern Methodist University at the address in this notice by June 29, 2020.

ADDRESSES: B. Sunday Eiselt, Department of Anthropology, Southern Methodist University, 3225 Daniel Avenue, Heroy Hall #450, Dallas, TX 75205, telephone (214) 768–2915, email *seiselt@smu.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the Department of Anthropology, Southern Methodist University, Dallas, TX. The human remains and associated funerary objects were removed from Henderson County, TX; Wood County, TX; Red River County, TX; and Sabine and De Soto Parishes, LA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Department of Anthropology, Southern Methodist University professional staff in consultation with representatives of the Caddo Nation of Oklahoma.

History and Description of the Remains

At an unknown date, human remains representing, at minimum, three individuals were removed from Henderson County, TX. The human remains from this collection include 21 long bone fragments, one vertebra, and one metatarsal. The human remains were found with four chert bifaces and a projectile point of Cuney type (Turner et al. 2011). The age and cultural affiliations of the human remains are based on the projectile point, as no further contextual evidence is available. These cultural items are part of the Harper collection, which was donated by an avocational archeologist to Southern Methodist University (SMU) in 1967. The only provenience information provided for the human remains from the Harper collection is ''HE5''. Based on comparable provenience information for the other items he donated, it appears that Harper employed his own numbering system, together with a county abbreviation, to identify each site from which he removed particular items. The current Texas county with the designation ''HE'' is Henderson County. No known individuals were identified. The five associated funerary objects are four chert bifaces and one projectile point.

Between 1975 and 1979, human remains and associated funerary objects were removed during excavations undertaken by SMU ahead of construction of the Lake Fork Reservoir, in Wood County, TX. Although the primary objective of these excavations was to identify and preserve sites ahead of reservoir construction, artifact analysis was used to identify settlement patterns. Human remains were found at four sites—the Osborne Site, the Spoonbill Site, the Sandhill Site, and the Yantis Site.

Human remains representing, at minimum, one individual were removed from the Osborne Site (X41WD16/41WD73). Burial 1 contained cranial fragments, five tarsal and metatarsal fragments, and highly fragmentary long bone sections. No known individuals were identified. No associated funerary objects are present.

Human remains representing, at minimum, one individual were removed from the Spoonbill Site (X41WD109/41WD518). Burial 3 contained nearly complete cranial fragments, though no maxillary or mandibular structures survived. Only fragments of the post-cranial remains were excavated; they are still encased in soil. No known individuals were identified. The seven associated funerary objects are ceramic vessels.

Human remains representing, at minimum, one individual were removed from the Sandhill Site (X41WD108). As Burial 1 was badly deteriorated, only a few long bone fragments were excavated; they remain encased in soil. No known individuals were identified. The four associated funerary objects are ceramic vessels.

Human remains representing, at minimum, one individual were removed from the Yantis Site (X41WD27/41WD45). Burial 3 has few records associated with it beyond a note from Bob D. Skiles, an avocational archeologist who worked in the area. Fragments of a skull are encased in a limestone or plaster substance, so it is not possible to determine the extent to which the human remains are preserved. No known individuals were identified. No associated funerary objects are present.

In 1968, human remains representing, at minimum, 63 individuals were removed from the Sam Kaufman Site in Red River County, TX. Excavations funded by the National Park Service and conducted by Alan Skinner, an ARP Principle Investigator affiliated with SMU, were conducted in order to study the site before it was destroyed by flooding of the nearby Red River. Burial 1 is an adult of unknown age and sex; the human remains are extremely fragmentary. Burial 2 is an eight-year-old child of unknown sex. Burial 3 is an adult between 36–50 years old and likely female. Burial 4 is 50+ year-old male. Burial 5 is an adult female of unknown age range and exhibits arthritic lipping on the lower thoracic vertebrae. Burial 6 is 36–50 years old, likely female, and exhibits periostitis on the ulnae, radii, and tibiae. Burial 7 is an adult whose sex and age range is indeterminate. Burial 8 is a 36–50 year-old female, and exhibits arthritic lipping on lower thoracic vertebrae. Burial 9 has an unknown sex and age range. Skeletons 6 through 9 are part of the multiple burial feature. Skeleton 6 is a 36–50 year-old female. Skeleton 7 is 36–50 years-old and likely female. Skeleton 8 is a 36–50 year-old female. Skeleton 9 is a 19–35 year-old female. Skeletons 10 through 20 are part of the shaft burial feature. Skeleton 10 is a 13–14 year-old of indeterminate sex. Skeleton 11 is a 36–50 year-old male. Skeleton 12 is a 17–18 year-old and likely male. Skeleton 13 is a 36–50 year-old female. Skeleton 14 is a 36–50 year-old male. Skeleton 15 is a 36–50 year-old female exhibiting a green stain on the mastoid area of the left temporal bone. Skeleton 16 is a 36–50 year-old male, and exhibits some evidence of arthritic lipping and a green stain above the external auditory meatus. Skeleton 17 is a 36–50 year-old male. Skeleton 18 is a 36–50 year-old male. Skeleton 19 is a female, likely between 19–35 years old. Skeleton 20 is a 36–50 year-old male, and exhibits a thickened diploe layer on a cranial bone. The remaining 40 individuals are represented by one or a few skeletal elements. Their sex and age are unknown. No known individuals were identified. The 1,032 associated funerary objects are 12 individual and two lots of faunal bone, 42 stones, 111 individual and one lot of sherds, two pollen samples, 77 reconstructed pots, 652 beads, 64 individual and two lots of shell, 46 projectile points, seven lithic artifacts, one lot of dirt, five gorgets, onet copper sheet, two pipes, one red pigment, one green pigment, two celts, and one unknown artifact.

The Sam Kaufman Site is estimated by Alan Skinner, to date to the McCurtain phase (A.D. 1300–1700), *i.e.* the Caddo II (A.D. 1200–1400), Caddo III (A.D. 1400–1500), and Caddo IV (A.D. 1500–2700) periods. Pottery types found at this site are affiliated with the Caddo Nation of Oklahoma. The published report affiliates this site with the ancestral Caddo. The Caddo Nation of Oklahoma claims Red River County, TX, as an area of interest.

In 1966, human remains representing, at minimum, 12 individuals were removed from the Bison B Site (16SA4) in Sabine Parish, LA, by Principal Investigator Ned Woodall. The individuals from the Bison B Site (16SA4) are referred to by feature number. Feature 2 is an adolescent male 10–19 years old. Feature 4 is an adult male 20–50 years old. Feature 5 is an adolescent 10–19 years old, whose sex is indeterminate due to the fragmentary nature of the human remains. Features 6A and 6B were commingled; 6A is an adult 20–50 years old of indeterminate sex, and 6B is a child 1–10 years old of indeterminate sex. Feature 7 is an adult male 20–50 years old. Feature 8 is an adult female 20–50 years old. Feature 12 is an adult 20–50 years old of indeterminate sex due to the fragmentary nature of the human remains. Feature 14 is an adult female 20–50 years old. Feature 15 is an adolescent 10–19 years old of indeterminate sex. Feature 16 is a child 1–10 years old of indeterminate sex due to the fragmentary nature of the human remains. Feature 17 is an adult 20–50 years old of indeterminate sex. No known individuals were identified. The 143 associated objects are 29 projectile points, 66 vessels, one lump of clay, one biface, one pipe, one lot of yellow ochre pigment, one opossum mandible fragment, one fox squirrel faunal remains, 36 bone fragments, one sherd, one single-side notched dart point, one mussel shell, two ear spools, and one lot of green pigment.

In 1967–1968, human remains representing, at minimum, eight individuals were removed from site 16SA17 in Sabine Parish, LA, by James V. Sciscenti. Excavations funded by the National Park Service and conducted by the Archaeology Research Program affiliated with SMU prior to the inundation of the Toledo Bend Reservoir, on the border of Texas and Louisiana. Burial 1 is an adult 20–50 years old of indeterminate sex. Burial 2 is an adult 20–50 years old of indeterminate sex. Burial 3 is an adult male 20–50 years old. Burial 4 is an adult female 20–50 years old. Burial 5 is an adolescent 10–19 years old of indeterminate sex. Two cremations were found adjacent to one another in small, circular pits. There is no identifying information for Cremation 1. Cremation 2 is an older adult 50+ years old. A single finger bone from Lot 8–3 represents an adult of indeterminate sex. No known individuals were identified. No associated funerary objects are present.

In 1966, human remains representing, at minimum, one individual were removed from the James Pace Site (16DS10) in De Soto Parish, LA, by Harold P. Jensen. Burial 1 is an adult 20–50 years old of indeterminate sex due to the poor preservation of the human remains. No known individuals were identified. No associated funerary objects are present.

The Toledo Bend sites are estimated to date to the Alto Focus (A.D. 900–1200). Pottery types found at this site are affiliated with the Caddo Nation of Oklahoma. The published report affiliates this site with the ancestral Caddo. The Caddo Nation of Oklahoma claim Sabine and De Soto Parishes, LA, as areas of interest.

Determinations Made by the Department of Anthropology, Southern Methodist University

Officials of the Department of Anthropology, Southern Methodist University have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 91 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 1,191 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.

• Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and the Caddo Nation of Oklahoma.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to B. Sunday Eiselt, Department of Anthropology, Southern Methodist University, 3225 Daniel Avenue, Heroy Hall #450, Dallas, TX 75205, telephone (214) 768–2915, email *seiselt@smu.edu,* by June 29, 2020. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Caddo Nation of Oklahoma may proceed.

The Department of Anthropology, Southern Methodist University is responsible for notifying the Caddo Nation of Oklahoma that this notice has been published.

Dated: April 21, 2020.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2020–11567 Filed 5–28–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NER–ACAD–29902; PPNEACADSO, PPMPSPDIZ.YM0000]

Request for Nominations for the Acadia National Park Advisory Commission

AGENCY: National Park Service, Interior.

ACTION: Request for nominations.

SUMMARY: The National Park Service (NPS), U.S. Department of the Interior, is requesting nominations for qualified persons to serve as members of the Acadia National Park Advisory Commission (Commission).

DATES: Written nominations must be postmarked by June 29, 2020.

ADDRESSES: Nominations should be sent to Michael Madell, Deputy Superintendent, Acadia National Park, P.O. Box 177, Bar Harbor, Maine 04609, telephone (207) 288–8701, or email *michael_madell@nps.gov.*

FOR FURTHER INFORMATION CONTACT: Michael Madell, Deputy Superintendent, Acadia National Park, P.O. Box 177, Bar Harbor, Maine 04609, telephone (207) 288–8701, or email *michael_madell@nps.gov.*

SUPPLEMENTARY INFORMATION: The Commission was established by section 103 of Public Law 99–420, as amended, (16 U.S.C. 341 note), and in accordance with the Federal Advisory Committee Act (5 U.S.C. Appendix 1–16). The Commission advises the Secretary and the NPS on matters relating to the management and development of Acadia National Park, including but not limited to, the acquisition of lands and interests in lands (including conservation easements on islands) and the termination of rights of use and occupancy.

The Commission is composed of 16 members appointed by the Secretary, as follows: (a) Three members at large; (b) three members appointed from among individuals recommended by the Governor of Maine; (c) four members appointed from among individuals recommended by each of the four towns on the island of Mount Desert; (d) three members appointed from among individuals recommended by each of the three Hancock County mainland communities of Gouldsboro, Winter Harbor, and Trenton, and; (e) three members appointed from among individuals recommended by each of the three island towns of Cranberry Isles, Swans Island, and Frenchboro.

The NPS is seeking nominees to represent the towns of Cranberry Isles, Frenchboro, Swan Island, Winter Harbor, and members at large. Nominations received by the park will be sent directly to local municipalities for their consideration.

Nominations should be typed and should include a resume 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 Commission and permit the Department to contact a potential member. All documentation, including letters of recommendation, must be compiled and submitted in one complete package. All those interested in membership, including current members whose terms are expiring, must follow the same nomination process. Members may not appoint deputies or alternates.

Members of the Commission serve without compensation. However, while away from their homes or regular places of business in the performance of services for the Committee as approved by the NPS, members may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed intermittently in Government service are allowed such expenses under section 5703 of title 5 of the United States Code.

Public Disclosure of Information: Before including your address, phone number, email address, or other personal identifying information with your nomination, you should be aware that your entire nomination—including your personal identifying information—may be made publicly available at any time. While you can ask us in your nomination 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)

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2020–11611 Filed 5–28–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0030208; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Pueblo Grande Museum, Phoenix, AZ

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Pueblo Grande Museum, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural items listed in this notice meet the definition of unassociated funerary objects. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request to the Pueblo Grande Museum. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to the Pueblo Grande Museum at the address in this notice by June 29, 2020.

ADDRESSES: Lindsey Vogel-Teeter, Pueblo Grande Museum, 4619 E Washington Street, Phoenix, AZ 85034,

telephone (602) 534–1572, email *lindsey.vogel-teeter@phoenix.gov.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items under the control of the Pueblo Grande Museum, Phoenix, AZ, that meet the definition of unassociated funerary objects under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Items

Sometime prior to July 1953, six cultural items were removed from the vicinity of site NA3640, which is located in proximity to the argillite mines in Chino Valley, Yavapai County, AZ. In 1953, these objects were transferred to the Pueblo Grande Museum by private collectors Ida and Moulton Smith. Provenience information provided for the objects states they were ''. . .found in a shallow grave on Taylor land east of the prehistoric pipestone quarries north of Chino Valley in Yavapai County.'' The six unassociated funerary objects are four copper bells and two textile fragments. The unassociated funerary objects likely belong to the Sinagua Archeological Culture.

The Yavapai-Prescott Indian Tribe (previously listed as Yavapai-Prescott Tribe of the Yavapai Reservation, Arizona) trace their ancestry to bands once living in the Sinagua archeological cultural area.

Determinations Made by the Pueblo Grande Museum

Officials of the Pueblo Grande Museum have determined that:

- Pursuant to 25 U.S.C. 3001(3)(B), the six cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the six unassociated funerary objects and the Yavapai-Prescott Indian Tribe (previously listed as the Yavapai-Prescott Tribe of the Yavapai Reservation, Arizona).

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to Lindsey Vogel-Teeter, Pueblo Grande Museum, 4619 E Washington Street, Phoenix, AZ 85034, telephone (602) 534–1572, email *lindsey.vogel-teeter@phoenix.gov,* by June 29, 2020. After that date, if no additional claimants have come forward, transfer of control of the six unassociated funerary objects to the Yavapai-Prescott Indian Tribe (previously listed as the Yavapai-Prescott Tribe of the Yavapai Reservation, Arizona) may proceed.

The Pueblo Grande Museum is responsible for notifying the Yavapai-Prescott Indian Tribe (previously listed as the Yavapai-Prescott Tribe of the Yavapai Reservation, Arizona) that this notice has been published.

Dated: April 20, 2020.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2020–11560 Filed 5–28–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0030225; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Department of Anthropology, Southern Methodist University, Dallas, TX

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Department of Anthropology, Southern Methodist University has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Department of Anthropology, Southern Methodist University. If no additional requestors come forward, transfer of control of the human remains to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the Department of Anthropology, Southern Methodist University at the address in this notice by June 29, 2020.

ADDRESSES: B. Sunday Eiselt, Department of Anthropology, Southern Methodist University, 3225 Daniel Avenue, Heroy Hall #450, Dallas, TX 75205, telephone (214) 768–2915, email *seiselt@smu.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the Department of Anthropology, Southern Methodist University, Dallas, TX. The human remains were removed from Collin County, TX.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Department of Anthropology, Southern Methodist University professional staff in consultation with representatives of the Caddo Nation of Oklahoma; Coushatta Tribe of Louisiana; The Muscogee (Creek) Nation; Tonkawa Tribe of Indians of Oklahoma; and the Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma (hereafter referred to as ''The Tribes'').

History and Description of the Remains

At an unknown time, human remains representing, at minimum, one individual were removed from private property in Collin County, TX. Skull CC–405–98 was held by an individual living in Collin County, TX, and was surrendered to the Medical Examiner in 1998. Origins for the individual are unknown. Analysis done by the Collin County Medical Examiner concluded that the individual is Native American. The individual was transferred from the Collin County Medical Examiner's

Office to the Department of Anthropology at Southern Methodist University in 2006. No known individuals were identified. No associated funerary objects are present.

Determinations Made by the Department of Anthropology, Southern Methodist University

Officials of the Department of Anthropology, Southern Methodist University have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based upon skeletal analysis and geographical location.
- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and any present-day Indian Tribe.
- According to final judgments of the Indian Claims Commission or the Court of Federal Claims, the land from which the Native American human remains were removed is the aboriginal land of The Tribes.
- Pursuant to 43 CFR 10.11(c)(1), the disposition of the human remains may be to The Tribes.

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to B. Sunday Eiselt, Department of Anthropology, Southern Methodist University, 3225 Daniel Avenue, Heroy Hall #450, Dallas, TX 75205, telephone (214) 768–2915, email *seiselt@smu.edu,* by June 29, 2020. After that date, if no additional requestors have come forward, transfer of control of the human remains to The Tribes may proceed.

The Department of Anthropology, Southern Methodist University is responsible for notifying The Tribes that this notice has been published.

Dated: April 21, 2020.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2020–11568 Filed 5–28–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0030211; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Gilcrease Museum, Tulsa, OK

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Gilcrease Museum has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Gilcrease Museum. If no additional requestors come forward, transfer of control of the human remains to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the Gilcrease Museum at the address in this notice by June 29, 2020.

ADDRESSES: Laura Bryant, Gilcrease Museum, 1400 N Gilcrease Museum Road, Tulsa, OK 74127, telephone (918) 596–2747, email *laura-bryant@utulsa.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the Gilcrease Museum, Tulsa, OK. The human remains were removed from the tribal land of the Osage Nation.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Gilcrease Museum professional staff in consultation with representatives of The Osage Nation (previously listed as Osage Tribe).

History and Description of the Remains

Around 1900, human remains representing, at minimum, three individuals were removed from the tribal land of the Osage Nation. Emil Lenders, a painter and collector, traveled throughout the Plains around the turn of the century, and acquired three scalp locks (accession numbers 86.20a–b, 86.23) during this time. In 1950, Thomas Gilcrease purchased Lenders' collection, including these scalp locks. In 1955, Gilcrease transferred his collection to the City of Tulsa. The three individuals are of unknown age and sex. No known individuals were identified. No associated funerary objects are present.

The scalp locks of these three individuals were determined to be Native American through physical examination and provenance documentation. Lenders' collection notes identify the scalps as Osage, and the fact of their existence is consistent with Osage traditions at the time. Moreover, Lenders clearly had contact with the Osage, based on his travels and the provenience of other items from his collection.

Determinations Made by the Gilcrease Museum

Officials of the Gilcrease Museum have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of three individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and The Osage Nation (previously listed as Osage Tribe).

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Laura Bryant, Gilcrease Museum, 1400 N Gilcrease Museum Road, Tulsa, OK 74127, telephone (918) 596–2747, email *laura-bryant@utulsa.edu,* by June 29, 2020. After that date, if no additional requestors have come forward, transfer

of control of the human remains to The Osage Nation (previously listed as Osage Tribe) may proceed.

The Gilcrease Museum is responsible for notifying The Osage Nation (previously listed as Osage Tribe) that this notice has been published.

Dated: April 20, 2020.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2020–11562 Filed 5–28–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0030226; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Ball State University, Department of Anthropology, Muncie, IN

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Ball State University, Department of Anthropology has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and associated funerary objects and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the Ball State University, Department of Anthropology. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the Ball State University, Department of Anthropology at the address in this notice by June 29, 2020.

ADDRESSES: Kevin C. Nolan, Ball State University, Applied Anthropology Laboratories, 2000 University Avenue, Muncie, IN 47306, telephone (765) 285–5325, email *kcnolan@bsu.edu*.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the Ball State University, Department of Anthropology, Muncie, IN. The human remains and associated funerary objects were removed from site 12–St–214 in Starke County, IN, an unknown location near Knox in Stark County, IN, and site 12–Le–22, the Alt Site, in La Porte County, IN.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Ball State University, Department of Anthropology professional staff in consultation with representatives of the Citizen Potawatomi Nation, Oklahoma; Delaware Nation, Oklahoma; Eastern Band of Cherokee Indians; Eastern Shawnee Tribe of Oklahoma; Hannahville Indian Community, Michigan; Miami Tribe of Oklahoma; and the Pokagon Band of Potawatomi Indians, Michigan and Indiana.

The Absentee Shawnee Tribe of Indians of Oklahoma; Bad River Band of the Lake Superior Tribe of Chippewa Indians of the Bad River Reservation, Wisconsin: Bay Mills Indian Community, Michigan; Cherokee Nation; Chippewa Cree Indians of the Rocky Boy's Reservation, Montana (previously listed as Chippewa-Cree Indians of the Rocky Boy's Reservation, Montana); Delaware Tribe of Indians; Forest County Potawatomi Community, Wisconsin; Grand Traverse Band of Ottawa and Chippewa Indians, Michigan; Kaw Nation, Oklahoma; Keweenaw Bay Indian Community, Michigan; Kickapoo Traditional Tribe of Texas; Kickapoo Tribe of Indians of the Kickapoo Reservation in Kansas; Kickapoo Tribe of Oklahoma; Lac Courte Oreilles Band of Lake Superior Chippewa Indians of Wisconsin; Lac du Flambeau Band of Lake Superior Chippewa Indians of the Lac du Flambeau Reservation of Wisconsin; Lac Vieux Desert Band of Lake Superior Chippewa Indians of Michigan; Match-e-be-nash-she-wish Band of Pottawatomi Indians of Michigan; Minnesota Chippewa Tribe, Minnesota (Six component reservations: Bois Forte Band (Nett Lake); Fond du Lac Band; Grand Portage Band; Leech Lake Band; Mille Lacs Band; White Earth Band); Nottawaseppi Huron Band of the Potawatomi, Michigan (previously listed as Huron Potawatomi, Inc.); Omaha Tribe of Nebraska; Ottawa Tribe of Oklahoma; Peoria Tribe of Indians of Oklahoma; Ponca Tribe of Indians of Oklahoma; Ponca Tribe of Nebraska; Prairie Band Potawatomi Nation (previously listed as Prairie Band of Potawatomi Nation, Kansas); Quapaw Nation (previously listed as The Quapaw Tribe of Indians); Quechan Tribe of the Fort Yuma Indian Reservation, California & Arizona; Red Cliff Band of Lake Superior Chippewa Indians of Wisconsin; Red Lake Band of Chippewa Indians, Minnesota; Sac & Fox Nation of Missouri in Kansas and Nebraska; Sac & Fox Nation, Oklahoma; Sac & Fox Tribe of the Mississippi in Iowa; Saginaw Chippewa Indian Tribe of Michigan; Sault Ste. Marie Tribe of Chippewa Indians, Michigan; Seneca Nation of Indians (previously listed as Seneca Nation of New York); Seneca-Cayuga Nation (previously listed as Seneca-Cayuga Tribe of Oklahoma); Shawnee Tribe; Sokaogon Chippewa Community, Wisconsin; St. Croix Chippewa Indians of Wisconsin; Stockbridge Munsee Community, Wisconsin; The Osage Nation (previously listed as Osage Tribe); Tonawanda Band of Seneca (previously listed as Tonawanda Band of Seneca Indians of New York); Turtle Mountain Band of Chippewa Indians of North Dakota; Tuscarora Nation; United Keetoowah Band of Cherokee Indians in Oklahoma; and the Wyandotte Nation were invited to consult but did not participate.

Hereafter, all Tribes named in this section are referred to as ''The Consulted and Invited Tribes.''

History and Description of the Remains

In 1986, the human remains of, at minimum, one individual were removed from site 12–St–214 in Starke County, IN, during a Phase Ia pedestrian survey by Ball State University for the Michigan Precision Industries project. The site consisted primarily of fire-cracked rock (FCR), but also included lithic debitage. A total of 72 fragments of scattered cremated cranial and post-cranial bones belonging to an individual of unknown age and sex were recovered during the survey (catalogue #12–St–214–25). In 1996, the human remains of a second individual were recovered

from the site by Ball State University during work that included intensive surface collection, two test excavation units, and 11 trenches. The human remains consist of one fragment of calcined human humerus (catalogue #96.31.1.1.152). A test unit excavated at the location of the human remains did not yield any additional cultural materials or human remains. In 1999, a private collector donated the human remains of two additional individuals to the BSU Department of Anthropology (accession #99.45). According to the donor, one individual was collected from site 12–St–214 (catalogue #99.45.1) and the other was collected from a site north of Knox, IN, (catalogue #99.45.2). No known individuals were identified. The 428 associated funerary objects are six bifaces, 305 pieces of lithic debitage, six cores, three endscrapers, two gravers, eight other chipped stone, 11 slate, 46 bones, one drilled shell, two shell fragments, 37 sherds, and one mortar.

In 1978 and 1980, the human remains of, at minimum, 18 individuals were collected from site 12–Le–22, the Alt Site, in La Porte County, IN, during investigations by the Northwest Indiana Archaeological Association (NWIAA) together with archeologists from the University of Notre Dame (1978), and by the Indiana Department of Natural Resources, Division of Historic Preservation (1980). The human remains were donated to Ball State University in 1988 (accession number 88.025). Samples from select burials were included in an analysis of ancient DNA as part of a MA thesis presented to the Department of Anthropology, Ball State University. Five bone samples were tested in 1994 and 1995, but none yielded extractable DNA. No known individuals were identified. No associated funerary objects are present (artifacts are known to have been recovered during the 1978 and 1980 investigations, as well as by private collectors).

Determinations Made by the Ball State University, Department of Anthropology

Officials of the Ball State University, Department of Anthropology have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on the fact that they are associated prehistoric artifacts and animal bone.
- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 22 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 428 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and associated funerary objects and any present-day Indian Tribe.
- According to final judgments of the Indian Claims Commission or the Court of Federal Claims, the land from which the Native American human remains and associated funerary objects were removed is the aboriginal land of the Citizen Potawatomi Nation, Oklahoma; Forest County Potawatomi Community, Wisconsin; Hannahville Indian Community, Michigan; Match-e-be-nash-she-wish Band of Pottawatomi Indians of Michigan; Nottawaseppi Huron Band of the Potawatomi, Michigan (previously listed as Huron Potawatomi, Inc.); Pokagon Band of Potawatomi Indians, Michigan and Indiana; and the Prairie Band Potawatomi Nation (previously listed as Prairie Band of Potawatomi Nation, Kansas)(hereafter referred to as ''The Tribes'').
- Pursuant to 43 CFR 10.11(c)(1), the disposition of the human remains and associated funerary objects may be to The Tribes.

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Kevin C. Nolan, Ball State University, Applied Anthropology Laboratories, 2000 University Avenue, Muncie, IN 47306, telephone (765) 285–5325, email *kcnolan@bsu.edu,* by June 29, 2020. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to The Tribes may proceed.

The Ball State University, Department of Anthropology is responsible for notifying The Consulted and Invited Tribes that this notice has been published.

Dated: April 21, 2020.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2020–11569 Filed 5–28–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0030221; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Department of Anthropology, Southern Methodist University, Dallas, TX

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Department of Anthropology, Southern Methodist University has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Department of Anthropology, Southern Methodist University. If no additional requestors come forward, transfer of control of the human remains to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the Department of Anthropology, Southern Methodist University at the address in this notice by June 29, 2020.

ADDRESSES: B. Sunday Eiselt, Department of Anthropology, Southern Methodist University, 3225 Daniel Avenue, Heroy Hall #450, Dallas, TX 75205, telephone (214) 768–2915, email *seiselt@smu.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the Department of Anthropology, Southern Methodist University, Dallas, TX. The human remains were removed from Hunt County, TX.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has

control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Department of Anthropology, Southern Methodist University professional staff in consultation with representatives of the Apache Tribe of Oklahoma; Caddo Nation of Oklahoma; Comanche Nation, Oklahoma; Coushatta Tribe of Louisiana; The Muscogee (Creek) Nation; Tonkawa Tribe of Indians of Oklahoma; and the Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma (hereafter referred to as ''The Tribes'').

History and Description of the Remains

At an unknown date, human remains representing, at minimum, one individual were removed from Hunt County, TX. These human remains are part of the Harper collection. They are comprised of one well-worn molar with partial roots. The provenience information provided for this tooth is ''Greenville Hwy 67, Hunt County''. It appears that Harper employed his own system to identify each site from which he removed particular items. Here Harper used highway markers to indicate a general area. Since this is the only extant context information, it is not possible to assign an associated culture with these human remains. No known individual was identified. No associated funerary objects are present.

Determinations Made by the Department of Anthropology, Southern Methodist University

Officials of the Department of Anthropology, Southern Methodist University have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on geographical location.
- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and any present-day Indian Tribe.
- According to final judgements of the Indian Claims Commission or the Court of Federal Claims, the land from which the Native American human remains were removed is the aboriginal land of The Tribes.
- Pursuant to 43 CFR 10.11(c)(1), the disposition of the human remains may be to The Tribes.

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to B. Sunday Eiselt, Department of Anthropology, Southern Methodist University, 3225 Daniel Avenue, Heroy Hall #450, Dallas, TX 75205, telephone (214) 768–2915, email *seiselt@smu.edu,* by June 29, 2020. After that date, if no additional requestors have come forward, transfer of control of the human remains to The Tribes may proceed.

The Department of Anthropology, Southern Methodist University is responsible for notifying the Tribes that this notice has been published.

Dated: April 21, 2020.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2020–11564 Filed 5–28–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0030222; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Department of Anthropology, Southern Methodist University, Dallas, TX

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Department of Anthropology, Southern Methodist University (SMU) has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Department of Anthropology, Southern Methodist University. If no additional requestors come forward, transfer of control of the human remains to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the Department of Anthropology, Southern Methodist University at the address in this notice by June 29, 2020.

ADDRESSES: B. Sunday Eiselt, Department of Anthropology, Southern Methodist University, 3225 Daniel Avenue, Heroy Hall #450, Dallas, TX 75205, telephone (214) 768–2915, email *seiselt@smu.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the Department of Anthropology, Southern Methodist University, Dallas, TX. The human remains were removed from Dallas County, TX.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Department of Anthropology, Southern Methodist University professional staff in consultation with representatives of the Apache Tribe of Oklahoma; Comanche Nation, Oklahoma; Coushatta Tribe of Louisiana; Tonkawa Tribe of Indians of Oklahoma; and the Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Towakonie), Oklahoma (hereafter referred to as ''The Tribes'').

History and Description of the Remains

At an unknown date, human remains representing, at minimum, one individual were removed from the Hackberry Creek site in Dallas County, TX. The occupational timelines for Dallas County had been investigated multiple times by the Dallas Archaeological Society, The University of Texas, Arlington, and various CRM projects. No context is provided for the human remains, and it is not known if they are associated with the prehistoric artifacts from the site. An appendix by Harrell Gill-King, Ph.D., indicates that, more likely than not, all the bone fragments are from the same period. They are at least 200 years old, but their

age is ''probably much greater'' (Skinner and Ferring 1999).

As a result of previous construction activities in the area, multiple sites were eroded. Surface survey and excavation revealed large numbers of prehistoric artifacts. Skinner and Ferring (1999) concluded that there had been ''one or more'' occupations in this area over an extended period of time, but that the artifacts associated with these occupations had been redeposited by natural and human activities, and that, therefore, they are not in their original depositional context. Artifact analysis indicates that a Late Archaic occupation definitely was present, but it is unclear if there was also a Late Prehistoric occupation. No artifacts were associated with the burial, because the specific context of the human remains is unknown. The definitive age of the burial is currently unknown. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed from the Hutchins Sand and Gravel Yard in Dallas County, TX. The only provenience information provided for these long bone fragments is ''Hutchins Sand and Gravel Yard, about half a mile from the Trinity River.'' This yard, in Dallas County, TX, is unrelated to any SMU excavation project. Dr. Meltzer determined that the bones postdated the Pleistocene period stratum below them, but that their context may have been disturbed. Since this is the only extant contextual information, it is not possible to assign these human remains to a time period or culture, or even associate them with any artifacts. No known individual was identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, one individual were removed from Rowlett Creek in Dallas County, TX. The only provenience information provided for these bone fragments is ''Rowlett Creek, 1980''. Presumably, the reference is to the Rowlett Creek that runs through Dallas County. The only known project related to Rowlett Creek was completed by AR Consultants and reported by Alan Skinner in 1990. No human remains, however, were identified during that project and, ultimately, the excavators determined that the only sign of occupation was a historic house in the Rowlett Creek Park area. Although the artifacts were connected to a collection of lithics, those lithics are just flakes and fire-cracked rock that are not indicative of a time period or culture. Moreover, the Skinner report indicates that the area was heavily eroded, and that no visible secure contexts were visible. Since this is the only extent contextual information, it is not possible to assign an associated time period or culture to these human remains. No known individual was identified. No associated funerary objects are present.

Determinations Made by the Department of Anthropology, Southern Methodist University

Officials of the Department of Anthropology, Southern Methodist University have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on geographical location.
- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of three individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and any present-day Indian Tribe.
- According to final judgments of the Indian Claims Commission or the Court of Federal Claims, the land from which the Native American human remains were removed is the aboriginal land of The Tribes.
- Pursuant to 43 CFR 10.11(c)(1), the disposition of the human remains may be to The Tribes.

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to B. Sunday Eiselt, Department of Anthropology, Southern Methodist University, 3225 Daniel Avenue, Heroy Hall #450, Dallas, TX 75205, telephone (214) 768–2915, email *seiselt@smu.edu,* by June 29, 2020. After that date, if no additional requestors have come forward, transfer of control of the human remains to The Tribes may proceed.

The Department of Anthropology, Southern Methodist University is responsible for notifying The Tribes that this notice has been published.

Dated: April 21, 2020.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2020–11565 Filed 5–28–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0030220; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Department of Anthropology, Southern Methodist University, Dallas, TX

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Department of Anthropology, Southern Methodist University (SMU) has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Department of Anthropology, Southern Methodist University. If no additional requestors come forward, transfer of control of the human remains to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the Department of Anthropology, Southern Methodist University at the address in this notice by June 29, 2020.

ADDRESSES: B. Sunday Eiselt, Department of Anthropology, Southern Methodist University, 3225 Daniel Avenue, Heroy Hall #450, Dallas, TX 75205, telephone (214) 768–2915, email *seiselt@smu.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the Department of Anthropology, Southern Methodist University, Dallas, TX. The human remains were removed from Somervell County, TX.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has

control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Department of Anthropology, Southern Methodist University professional staff in consultation with representatives of the Apache Tribe of Oklahoma; Coushatta Tribe of Louisiana; Delaware Nation, Oklahoma; Tonkawa Tribe of Indians of Oklahoma; and the Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma (hereafter referred to as ''The Tribes'').

History and Description of the Remains

At an unknown date, human remains representing, at minimum, one individual were removed from Somervell County, TX. The only provenience information provided for these long bone fragments is ''41SV''. This is the state and county designation for Somerville, TX. Only SMU worked on the Squaw Creek Reservoir project in Somerville. Consequently, SMU has determined that more likely than not, these human remains derive from that project. Since this is the only extant contextual information, it is impossible to associate the human remains with any artifacts from the site. Consequently, these human remains cannot be assigned to any time period or culture. No known individual was identified. No associated funerary objects are present.

Determinations Made by the Department of Anthropology, Southern Methodist University

Officials of the Department of Anthropology, Southern Methodist University have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American, based on geographical location.
- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and any present-day Indian Tribe.
- According to final judgements of the Indian Claims Commission or the Court of Federal Claims, the land from which the Native American human remains were removed is the aboriginal land of The Tribes.
- Pursuant to 43 CFR 10.11(c)(1), the disposition of the human remains may be to The Tribes.

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to B. Sunday Eiselt, Department of Anthropology, Southern Methodist University, 3225 Daniel Avenue, Heroy Hall #450, Dallas, TX 75205, telephone (214) 768–2915, email *seiselt@smu.edu,* by June 29, 2020. After that date, if no additional requestors have come forward, transfer of control of the human remains to The Tribes may proceed.

The Department of Anthropology, Southern Methodist University is responsible for notifying The Tribes that this notice has been published.

Dated: April 21, 2020.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2020–11563 Filed 5–28–20; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. TA–131–046 and TPA–105–007]

U.S.-Kenya Trade Agreement: Advice on the Probable Economic Effect of Providing Duty-Free Treatment for Currently Dutiable Imports Institution of Investigation and Scheduling of Hearing

AGENCY: United States International Trade Commission.

ACTION: Notice of investigation and scheduling of a public hearing.

SUMMARY: Following receipt on March 17, 2020, of a request from the United States Trade Representative (USTR), the Commission instituted Investigation Nos. TA–131–046 and TPA–105–007, *U.S.-Kenya Trade Agreement: Advice on the Probable Economic Effect of Providing Duty-free Treatment for Currently Dutiable Imports.*

DATES:

June 10, 2020: Deadline for filing requests to appear at the public hearing.

June 12, 2020: Deadline for filing prehearing briefs and statements.

July 7, 2020: Public hearing.

July 14, 2020: Deadline for filing post-hearing briefs and submissions.

July 14, 2020: Deadline for filing all other written statements.

September 16, 2020: Transmittal of Commission report to the USTR.

Because COVID–19 mitigation measures are in effect, the Commission will hold the public hearing using Go To Meeting. For further information on the hearing, see the section below on ''public hearing'' and also the Commission's ongoing investigations website (*https://usitc.gov/research_and_analysis/what_we_are_working_on.htm*), before July 7, 2020 for details about the hearing format.

ADDRESSES: All Commission offices are located in the United States International Trade Commission Building, 500 E Street SW, Washington, DC. All written submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW, Washington, DC 20436. The public record for this investigation may be viewed on the Commissions electronic docket (EDIS) at *https://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: Caroline Peters, Project Leader, (202–708–1433 or *caroline.peters@usitc.gov*), or Erika Bethmann, Deputy Project Leader (202–205–3001 or *erika.bethmann@usitc.gov*), for information specific to this investigation. For information on the legal aspects of this investigation, contact William Gearhart of the Commission's Office of the General Counsel (202–205–3091 or *william.gearhart@usitc.gov*). The media should contact Margaret O'Laughlin, Office of External Relations (202–205–1819 or *margaret.olaughlin@usitc.gov*). Hearing-impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at 202–205–1810. General information concerning the Commission may also be obtained by accessing its website (*http://www.usitc.gov*). Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

Background: In his letter of March 17, 2020, the USTR requested that the Commission provide certain advice under section 131 of the Trade Act of 1974 (19 U.S.C. 2151) and an assessment under section 105(a)(2)(B)(i)(III) of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 (19 U.S.C. 4204(a)(2)(B)(i)(III) with respect to the effects of providing duty-free treatment for imports of products from Kenya.

More specifically, the USTR, under authority delegated by the President and pursuant to section 131 of the Trade Act of 1974, requested that the Commission

provide a report containing its advice as to the probable economic effect of providing duty-free treatment for imports of currently dutiable products from Kenya on (i) industries in the United States producing like or directly competitive products, and (ii) consumers. The USTR asked that the Commission's analysis consider each article in chapters 1 through 97 of the *Harmonized Tariff Schedule of the United States* (HTS) for which U.S. tariffs will remain, taking into account implementation of U.S. commitments in the World Trade Organization. The USTR asked that the advice be based on the HTS in effect during 2020 and trade data for 2019.

In addition, the USTR requested that the Commission prepare an assessment, as described in section 105(a)(2)(B)(i)(III) of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015, of the probable economic effects of eliminating tariffs on imports from Kenya of those agricultural products described in the list attached to the USTR's request letter on (i) industries in the United States producing the products concerned, and (ii) the U.S. economy as a whole. The USTR's request letter and list of agricultural products are posted on the Commission's website at *http://www.usitc.gov.*

The Commission will provide its report to the USTR by September 16, 2020, or as soon as possible. The USTR indicated that those sections of the Commission's report that relate to the advice and assessment of probable economic effects will be classified. The USTR also indicated that he considers the Commission's report to be an interagency memorandum that will contain pre-decisional advice and be subject to the deliberative process privilege.

Public Hearing: A public hearing in connection with this investigation will be held beginning at 9:30 a.m. on July 7, 2020, using Go To Meeting. Information about the hearing, will be posted on the Commission's website at (*https://usitc.gov/research_and_analysis/what_we_are_working_on.htm*). Once on that web page, scroll down to the entry for Investigation No. 131–046, *U.S.-Kenya Trade Agreement: Advice on the Probable Economic Effect of Providing Duty-free Treatment for Currently Dutiable Imports,* and click on the link to ''hearing instructions.'' Requests to appear at the public hearing should be filed with the Secretary no later than 5:15 p.m., June 10, 2020, in accordance with the requirements in the ''Written Submissions'' section below. All prehearing briefs and statements should be filed not later than 5:15 p.m., June 12, 2020, and all post-hearing briefs and statements should be filed not later than 5:15 p.m., July 14, 2020. All requests to appear, and pre- and post-hearing briefs and statements should be filed in accordance with the requirements of the ''written submissions'' section below.

Written Submissions: In lieu of or in addition to participating in the hearing, interested parties are invited to file written submissions concerning this investigation. All written submissions should be addressed to the Secretary, and should be received not later than 5:15 p.m., July 14, 2020. All written submissions must conform to the provisions of section 201.8 of the Commission's Rules of Practice and Procedure (19 CFR 201.8), as temporarily amended by 85 FR 15798 (March 19, 2020). Under that rule waiver, the Office of the Secretary will accept only electronic filings at 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 electronic filing should contact the Office of the Secretary, Docket Services Division (202–205–1802) or consult the Commission's Handbook on Filing Procedures.

Confidential Business Information: Any submissions that contain confidential business information must also conform to the requirements of section 201.6 of the Commission's Rules of Practice and Procedure (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the ''confidential'' or ''nonconfidential'' version, and that the confidential business information is clearly identified by means of brackets. All written submissions, except for confidential business information, will be made available for inspection by interested parties.

The Commission may include some or all of the confidential business information submitted in the course of this investigation in the report it sends to the USTR. Additionally, all information, including confidential business information, submitted in 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 (a) for cybersecurity purposes or (b) in monitoring user activity on U.S. government classified networks. The Commission will not otherwise disclose any confidential business information in a way that would reveal the operations of the firm supplying the information.

Summaries of Written Submissions: Persons wishing to have a summary of their position included in the report should include a summary with their written submission and should mark the summary as having been provided for that purpose. The summary should be clearly marked as ''summary for inclusion in the report'' at the top of the page. The summary may not exceed 500 words, should be in MS Word format or a format that can be easily converted to MS Word, and should not include any confidential business information. The summary will be published as provided if it meets these requirements and is germane to the subject matter of the investigation. The Commission will list the name of the organization furnishing the summary and will include a link to the Commission's Electronic Document Information System (EDIS) where the full written submission can be found.

By order of the Commission.

Issued: May 26, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–11600 Filed 5–28–20; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–651]

Importer of Controlled Substances Application: Agilent Technologies

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before June 29, 2020. Such persons may also file a written request for a hearing on the application on or before June 29, 2020.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA **Federal Register** Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing must

be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All request for a hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA **Federal Register** Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on May 11, 2020, Agilent Technologies, 250 Smith Street, North Kingstown, Rhode Island 02852, applied to be registered as an importer of the following basic class(es) of controlled substances:

Controlled substance	Drug code	Schedule
Marihuana	7360	I
Tetrahydrocannabinols	7370	I

The company plans to import the listed controlled substances in bulk form for testing and calibration only. The listed controlled substances are not for human or animal use. No other activities for these drug codes are authorized for this registration.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2020–11546 Filed 5–28–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[CPCLO Order No. 004–2020]

Privacy Act of 1974; Systems of Records

AGENCY: Executive Office for Immigration Review, United States Department of Justice.

ACTION: Notice of a modified system of records.

SUMMARY: Pursuant to the Privacy Act of 1974, and Office of Management and Budget (OMB) Circular No. A–108, notice is hereby given that the Executive Office for Immigration Review (hereinafter EOIR), a component within the United States Department of Justice (DOJ) or (Department), proposes to update and reissue a current DOJ System of Records, entitled EOIR–003 Practitioner Complaint-Disciplinary Files. EOIR–003 will be renamed, ''Attorney Discipline System.'' The component proposes this update and reissuance to notify the public of the expanded functionality of this system, which now includes records of the adjudications of Attorney Discipline proceedings. This system will also adopt new and modified routine uses to better reflect the operational use of the system.

DATES: In accordance with 5 U.S.C. 552a(e)(4) and (11), this notice is effective upon publication, subject to a 30-day period in which to comment on the routine uses, described below. Please submit any comments by June 29, 2020.

ADDRESSES: The public, OMB, and Congress are invited to submit any comments to the United States Department of Justice, Office of Privacy and Civil Liberties, ATTN: Privacy Analyst, 145 N Street NE, Suite 8W.300, Washington, DC 20530, or by facsimile at 202–307–0693 or by email at *privacy.compliance@usdoj.gov.* To ensure proper handling, please reference the above CPCLO Order No. on your correspondence.

FOR FURTHER INFORMATION CONTACT: Michelle Curry, EOIR Senior Component Official for Privacy, EOIR Office of the General Counsel, 5107 Leesburg Pike Suite 2600, Falls Church, VA 22041, or by phone at 703–305–0990, or by email at *michelle.curry@usdoj.gov.*

SUPPLEMENTARY INFORMATION: To protect the public, preserve the integrity of immigration proceedings and adjudications, and maintain high professional standards among immigration practitioners, EOIR implemented the regulation, ''Professional Conduct for Practitioners—Rules and Procedures,'' 65 FR 39513 (June 27, 2000). EOIR modified the rule in 2008 to increase the number of grounds for discipline, improve the clarity and uniformity of the rules, and incorporate miscellaneous technical and procedural changes. *See* ''Professional Conduct for Practitioners—Rules and Procedures, and Representation and Appearances,'' 73 FR 76914 (Dec. 18, 2008). Effective January 18, 2017, the rules were again amended to extend discipline to recognized organizations and to make minor modifications to the reinstatement process. *See* ''Recognition of Organizations and Accreditation of Non-Attorney Representatives,'' 81 FR 92346 (Dec. 19, 2016). The term ''practitioners'' applies to attorneys and representatives who are authorized to represent aliens (but not attorneys representing the government) before EOIR's immigration court and the Board of Immigration Appeals (BIA or Board), EOIR's appellate component. The 2017 rule amendments have resulted in revisions to the Attorney Discipline System.

The EOIR Attorney Discipline Program resides in the Office of the General Counsel (OGC). Proceedings created as a result of the Attorney Discipline Program may include paper and electronic files created by the Disciplinary Counsel, who is the program lead, attorneys supporting the program, or program staff, and paper and electronic adjudication files of the BIA, the Office of Chief Immigration Judge (OCIJ), and/or the Office of the Chief Administrative Hearing Officer (OCAHO). The new Attorney Discipline System expands the prior system by developing an electronic database that contains information to track complaints from receipt through final disposition. The system is segregated by need to know user controls and allows authorized users to track various stages of the proceedings. The system also contains templates to generate letters, notices, and decisions used in the attorney discipline process. The system can generate reports by case status and disposition.

EOIR has applied routine uses to this system. Having these routine uses permits EOIR the necessary flexibility to disclose information in ways that are compatible with the purposes for which the information was collected. Specifically, EOIR has modified the language in the routine uses in paragraphs: 1–7; 9; 11 and 12 to conform their language to the current DOJ practice to describe the adopted uses. These modifications do not materially affect pre-existing routine uses as they are merely stylistic changes. EOIR has added a new routine use 10 to inform the public that the system and Attorney Discipline Program may be supported by contractors, grantees, experts, consultants, or students who will access the system on a need to know basis when necessary to accomplish an agency function related to this system of records. EOIR has also added new routine use 13, to address information release(s) in the event of a suspected or confirmed breach of the system, consistent with OMB guidance to federal agencies (OMB Memorandum 17–12, Preparing for and Responding to a Breach of Personally Identifiable Information (PII)). Finally, EOIR has added routine use 14 to allow release to third-party entities or individuals to the extent deemed necessary to elicit information from them or their cooperation to carry out authorized activities of EOIR.

Certain Privacy Act exemptions apply to this system, as stated in EOIR–003 Practitioner Complaint-Disciplinary Files. These modifications to the SORN do not amend or otherwise impact those exemptions.

In accordance with 5 U.S.C. 552a(r), the Department has provided a report to OMB and Congress on this notice of a modified system of records.

Dated: May 5, 2020.

Peter Winn,

Acting Chief Privacy and Civil Liberties Officer, United States Department of Justice.

JUSTICE/EOIR–003

SYSTEM NAME AND NUMBER:

EOIR, Attorney Discipline System, EOIR–003.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

DOJ EOIR, 5107 Leesburg Pike, Suite 2600, Falls Church, Virginia 22041.

SYSTEM MANAGER(S):

EOIR Chief Information Officer, Office of Information Technology (OIT), 5109 Leesburg Pike, Suite 900, Falls Church, Virginia 22041 and EOIR Attorney Discipline Counsel, EOIR OGC, 5107 Leesburg Pike, Suite 2600, Falls Church, Virginia 22041.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Sec. 292 of the Immigration and Nationality Act, as amended at 8 U.S.C. 1103, and 8 CFR 292.3, 1292.3 *et seq.*

PURPOSE(S) OF THE SYSTEM:

The purpose of this system is to assist EOIR's Attorney Discipline Program in conducting disciplinary investigations and instituting disciplinary proceedings against immigration practitioners and recognized organizations who violate the EOIR rules of practice as set forth in 8 CFR 1003.101 *et seq.* and the BIA, OCIJ and OCAHO in adjudicating the proceedings. The records are used to track and provide documentation of, among other things, complaints, disciplinary investigations, formal proceedings, and decisions in proceedings instituted by EOIR. The information may be further used to generate statistical reports and various administrative records, including docket printouts. The scope of the system of records, as proposed, is commensurate with the purpose(s) of the system because the records collected are limited to those necessary to serve the Program's overarching goal of protecting the public and the integrity of immigration proceedings by taking and tracking complaints; conducting investigations; performing adjudications, and where appropriate and consistent with the Program's rules, publically publishing information regarding the discipline imposed as a result of the violation(s).

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system includes information pertaining to attorneys and representatives practicing before the Immigration Judges and the BIA and recognized organizations, as the subjects of allegations of misconduct. Records also include information about complainants, witnesses, adjudicators, and individuals representing practitioners.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system contains paper and electronic case-related information for the following categories of records:

- Disciplinary complaints;
- Acknowledgment letters;
- Preliminary inquiries;
- Investigative information, witness statements, and other evidentiary information;
- Complaint dispositions;
- Formal disciplinary proceedings; and
- Notices, orders, and decisions for the BIA, OCIJ, or OCAHO.

RECORD SOURCE CATEGORIES:

Law enforcement agencies, federal and state courts, state bar licensing authorities, state bar grievance and/or disciplinary agencies, immigration practitioners or recognized organizations, inquiries and/or complaints from witnesses or members of the general public, and/or statements and information compiled during investigation of complaints.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b), all or a portion of the records or information contained in this system of records may be disclosed as a routine use pursuant to 5 U.S.C. 552a(b)(3) under the circumstances or for the purposes described below, to the extent such disclosures are compatible with the purposes for which the information was collected:

(1) In an appropriate proceeding before a court, grand jury, or an administrative or adjudicative body before which DOJ, or any DOJ component or subdivision thereof, is authorized to appear and when any of the following is a party to litigation or has an interest in litigation and such records are determined by DOJ to be arguably relevant to the proceeding; DOJ or any DOJ components thereof; any DOJ employee in his or her official capacity; any DOJ employee in his/her individual capacity where DOJ has agreed to represent the employee; or the United States where DOJ, or any DOJ component thereof, determines that litigation is likely to affect it or any of its subdivisions;

(2) To an actual or potential party, including an immigration practitioner, or to the party's attorney of record or authorized representative for the purpose of: Negotiation or discussion of matters such as settlement, conducting informal discovery proceedings involving records in this system, or to otherwise ensure fair representation;

(3) To complainants or their representatives of record to the extent necessary to provide such persons with information and explanations concerning the progress and/or results of the investigation or case arising from the matters of which they complained and/or of which they were a victim;

(4) To Federal, state, local, territorial, tribal, foreign, or international licensing agencies or associations, including, but not limited to, state bar grievance committees and other attorney discipline authorities, for possible disbarment or other disciplinary proceedings;

(5) Where a record, either alone or in conjunction with other information, indicates a violation or potential violation of law—criminal, civil, or regulatory in nature—the relevant records may be referred to the appropriate federal, state, local, territorial, tribal, or foreign law enforcement authority or other appropriate entity charged with the responsibility for investigating or prosecuting such violation or with enforcing or implementing such law;

(6) To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record;

(7) To the news media and the public, including disclosures pursuant to 28 CFR 50.2 unless it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy;

(8) To any federal agency or to any individual or organization for the purpose of performing audit or oversight operations of DOJ and to meet related reporting requirements;

(9) To the National Archives and Records Administration (NARA) for

purposes of records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906;

(10) To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the federal government, when necessary to accomplish an agency function related to this system of records;

(11) To a former employee of the Department for purposes of: Responding to an official inquiry by a federal, state, or local government entity or professional licensing authority, in accordance with applicable Department regulations; or facilitating communications with a former employee that may be necessary for personnel-related or other official purposes where the Department requires information and/or consultation assistance from the former employee regarding a matter within that person's former area of responsibility;

(12) To appropriate agencies, entities, and persons when the Department: Suspects or has confirmed that there has been a breach of the system of records; has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the Department (including its information systems, programs, and operations), the Federal Government, or national security; and when the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Department efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm;

(13) To another federal agency or federal entity, when the Department determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in: Responding to a suspected or confirmed breach or preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach;

(14) To any person or entity that EOIR has reason to believe possesses information regarding a matter within the jurisdiction of the EOIR, to the extent deemed to be necessary by EOIR in order to elicit such information or cooperation from the recipient for use in the performance of an authorized activity by EOIR.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records will be electronic and stored in secure EOIR databases. Temporary paper copies will be stored in secure locations and locked cabinets when not in use.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Electronic records may be retrieved from the Attorney Discipline System database by authorized personnel based on need-to-know restricted access permissions using the assigned case number or by the practitioner's name. Paper records may be retrieved by authorized personnel for mission purposes, as necessary, from secure storage locations where they are arranged by case type, disposition schedule, and case number in numerical order.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are maintained in hard-copy, paper format in secure filing cabinets. Electronic data is stored in electronic media via a configuration of government servers. Records are retained and disposed of in accordance with National Archives and Records Administration schedule DAA–0582–2017–0002.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Information in this system is maintained in accordance with applicable laws, rules, and policies on protecting individual privacy. Servers storing electronic data and backup tapes stored on-site are located in locked rooms with access restrictions limited to authorized agency personnel. Backup tapes stored off-site are maintained in accordance with applicable laws, rules, and policies. Internet connections are protected by multiple firewalls. Security personnel conduct periodic vulnerability scans using DOJ-approved software to ensure security compliance, and security logs are enabled for all computers to assist in troubleshooting and forensics analysis during incident investigations. Users of individual computers can only gain access to the data by a valid user identification and authentication process. The information maintained in the system is segregated in order to prevent ex-parte communications between adjudicators and OGC Disciplinary Counsel. Paper records are also segregated, and stored in secure locations with locked cabinets accessible only to those with a need to access the information.

RECORD ACCESS PROCEDURES:

Portions of this system may be exempt from disclosure and contest pursuant to 5 U.S.C. 552a(k)(1) and (k)(2). Any individual desiring to contest or amend information not subject to exemption must direct his/her request to the Senior Component Official for Privacy at the EOIR OGC. In all cases, requests for access to a record shall be made in writing. Written requests may be submitted by mail or in person. Written requests must be clearly marked and labeled ''Privacy Access Request,'' and the full name and notarized signature of the individual who is the subject of the record and any other identifying number or information that may assist in locating the record must be provided in accordance with 28 CFR 16.41(d), and a return address.

CONTESTING RECORD PROCEDURES:

All requests to contest or amend information maintained in the system will be directed to the Senior Component Official for Privacy at the EOIR OGC in the manner described above in the Record Access Procedures section. Requests should state clearly and concisely what information is being contested, the reasons for contesting it, and the proposed amendment to the information.

NOTIFICATION PROCEDURES:

Portions of this system may be exempt from disclosure and contest pursuant to 5 U.S.C. 552a(k)(1) and (k)(2). Any individual desiring to contest or amend information not subject to exemption must direct his/her request to the Senior Component Official for Privacy at the EOIR OGC. In all cases, requests for access to a record must be made in writing. Written requests may be submitted by mail or in person. Written requests must be clearly marked and labeled ''Privacy Access Request,'' and the full name and notarized signature of the individual who is the subject of the record and any other identifying number or information that may assist in locating the record must be provided in accordance with 28 CFR 16.41(d), and a return address.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

The Attorney General has previously exempted certain records of this system from the access provisions of the Privacy Act (5 U.S.C. 552a(d), pursuant to 5 U.S.C. 552a(k)(1) and (k)(2)). (*See* 28 CFR 16.83 (c) and (d)).

HISTORY:

EOIR–003 Practitioner Complaint-Disciplinary Files issued 64 FR 49237 (Sept. 10, 1999); 66 FR 8425 (Jan. 31,

2001); 72 FR 3410 (Jan. 25, 2007) amended to include exemptions claimed pursuant to 5 U.S.C. 552a(k)(1), and (k)(2), *See* 28 CFR 16.83.

[FR Doc. 2020–11528 Filed 5–28–20; 8:45 am]

BILLING CODE 4410–30–P

DEPARTMENT OF JUSTICE

[OMB Number 1105–0102]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Guam World War II Loyalty Recognition Program Statement of Claim

AGENCY: Foreign Claims Settlement Commission, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Foreign Claims Settlement Commission (Commission), Department of Justice (DOJ), 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.

DATES: Comments are encouraged and will be accepted for 30 days until June 29, 2020.

FOR FURTHER INFORMATION CONTACT: 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 Foreign Claims Settlement Commission, 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:* Extension.

2. *The Title of the Form/Collection:* Statement of Claim for filing of Claims in the Guam Claims Program Pursuant to the Guam World War II Loyalty Recognition Act, Title XVII, Public Law 114–328 (December 23, 2016)

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* FCSC–2. Foreign Claims Settlement Commission, Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Individuals.

Other: Estates.

Abstract: Information will be used as a basis for the Commission to receive, examine, adjudicate and render final decisions with respect to claims for compensation of claims pursuant to the Guam World War II Loyalty Recognition Act, Title XVII, Public Law 114–328 (December 23, 2016).

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 5,000 individual respondents will complete the application, and that the amount of time estimated for an average respondent to reply is approximately two hours each.

6. *An estimate of the total public burden (in hours) associated with the collection:* 10,000 annual burden hours.

If additional information is required contact: Melody D. Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: May 26, 2020.

Melody D. Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2020–11599 Filed 5–28–20; 8:45 am]

BILLING CODE 4410–BA–P

NUCLEAR REGULATORY COMMISSION

[NRC–2019–0100]

Safety Related Concrete Structures for Nuclear Power Plants (Other Than Reactor Vessels and Containments)

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory guide; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Revision 3 of Regulatory Guide (RG) 1.142, ''Safety Related Structures for Nuclear Power Plants (Other than Reactor Vessels and Containments).'' The guide was revised to endorse an updated version of American Concrete Institute code (ACI) 349–2013, ''Code Requirements for Nuclear Safety-Related Concrete Structures and Commentary.''

DATES: Revision 3 to RG 1.142 is available on May 29, 2020.

ADDRESSES: Please refer to Docket ID NRC–2019–0100 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–2019–0100. Address questions about NRC dockets IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public 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.*

Revision 3 to RG 1.142 and the regulatory analysis may be found in ADAMS under Accession Nos. ML20141L613 and ML16172A239, respectively.

Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them.

FOR FURTHER INFORMATION CONTACT: Madhumita Sircar, telephone: 301–415–1804; email: *Madhumita.Sircar@nrc.gov,* and Edward O'Donnell, telephone: 301–415–3317; email: *Edward.Odonnell@*

nrc.gov. Both are staff members of the Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Discussion

The NRC is issuing a revision to an existing guide in the NRC's ''Regulatory Guide'' series. This series was developed to describe and make available to the public information regarding methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, techniques that the NRC staff uses in evaluating specific issues or postulated events, and data that the NRC staff needs in its review of applications for permits and licenses.

Revision 3 of RG 1.142 was issued with a temporary identification of Draft Regulatory Guide, DG–1283. This revision (Revision 3) of RG 1.142 endorses, with certain exceptions, American Concrete Institute (ACI) 349–13, ''Code Requirements for Nuclear Safety-Related Concrete Structures and Commentary,'' except for Appendix D, ''Anchoring to Concrete.'' Appendix D to ACI 349–13 is addressed by RG 1.199, ''Anchoring Components and Structural Supports in Concrete.''

II. Additional Information

The NRC published a notice of the availability of DG–1283 in the **Federal Register** on April 23, 2019 (84 FR 16897) for a 60-day public comment period. The public comment period closed on June 24, 2019. Public comments on DG–1283 and the staff responses to the public comments are available under ADAMS under Accession No. ML20141L614.

III. Congressional Review Act

This RG is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

IV. Backfitting, Forward Fitting, and Issue Finality

Issuance of this regulatory guide does not constitute backfitting as defined in title 10 of the Code of Federal Regulations (10 CFR) section 50.109, ''Backfitting,'' and as described in NRC Management Directive 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests''; constitute forward fitting as that term is defined and described in Management Directive 8.4; or affect issue finality of any approval issued under 10 CFR part 52, ''Licenses, Certificates, and Approvals for Nuclear Power Plants.'' As explained in this regulatory guide, applicants and licensees are not required to comply with the positions set forth in this regulatory guide.

Dated: May 22, 2020.

For the Nuclear Regulatory Commission.

Edward F. O'Donnell,

Acting Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2020–11515 Filed 5–28–20; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 52–025 and 52–026; NRC–2008–0252]

Southern Nuclear Operating Company, Inc.; Vogtle Electric Generating Plant, Units 3 and 4; Auxiliary Building Room Heat-Up

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption and combined license amendment; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is granting an exemption to allow a departure from the certification information of Tier 1 of the generic design control document (DCD) and is issuing License Amendment Nos. 181 and 180 to Combined Licenses (COLs), NPF–91 and NPF–92, respectively. The COLs were issued to Southern Nuclear Operating Company, Inc., and Georgia Power Company, Oglethorpe Power Corporation, MEAG Power SPVM, LLC, MEAG Power SPVJ, LLC, MEAG Power SPVP, LLC, and the City of Dalton, Georgia (collectively SNC); for construction and operation of the Vogtle Electric Generating Plant (VEGP) Units 3 and 4, located in Burke County, Georgia. The granting of the exemption allows the changes to Tier 1 information asked for in the amendment. Because the acceptability of the exemption was determined in part by the acceptability of the amendment, the exemption and amendment are being issued concurrently.

DATES: The exemption and amendment were issued on May 12, 2020.

ADDRESSES: Please refer to Docket ID NRC–2008–0252 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–2008–0252. Address questions about NRC Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; e-mail: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public 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.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document. The request for the amendment and exemption was designated License Amendment Request (LAR) 19–010 and submitted by letter dated November 22, 2019 (ADAMS Accession No. ML19326D430).

FOR FURTHER INFORMATION CONTACT: Billy Gleaves, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–5848; email: *Bill.Gleaves@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is issuing License Amendment Nos. 181 and 180 to COLs NPF–91 and NPF–92, respectively, and is granting an exemption from Tier 1 information in the plant-specific DCD for the AP1000. The AP1000 DCD is incorporated by reference in Appendix D, ''Design Certification Rule for the AP1000,'' to part 52 of title 10 of the *Code of Federal Regulations* (10 CFR). The exemption, granted pursuant to Paragraph A.4 of Section VIII, ''Processes for Changes and Departures,'' of 10 CFR part 52, appendix D, allows the licensee to depart from the Tier 1 information. With the requested amendment, SNC sought proposed changes to the VEGP Tier 2 Updated Final Safety Analysis Report (UFSAR) and related changes to plant-specific Tier 1 information and the associated COL Appendix C. Specifically, the LAR requested a departure from current Tier 2 UFSAR information as well as changes to the plant-specific Tier 1 (and associated COL Appendix C) information in Table

2.2.5–4 that identified the heat loads for the auxiliary building rooms containing instrumentation and controls (I&C) and direct current (dc) power electrical equipment. The changes proposed in this LAR applied only to auxiliary building rooms outside the main control room envelope (MCRE).

Part of the justification for granting the exemption was provided by the review of the amendment. Because the exemption is necessary in order to issue the requested license amendment, the NRC granted the exemption and issued the amendment concurrently, rather than in sequence. This included issuing a combined safety evaluation containing the NRC staff's review of both the exemption request and the license amendment. The exemption met all applicable regulatory criteria set forth in §§ 50.12, 52.7, and section VIII.A.4 of appendix D to 10 CFR part 52. The license amendment was found to be acceptable as well. The combined safety evaluation is available in ADAMS under Accession No. ML20059N793.

Identical exemption documents (except for referenced unit numbers and license numbers) were issued to SNC for VEGP Units 3 and 4 (COLs NPF–91 and NPF–92). The exemption documents for VEGP Units 3 and 4 can be found in ADAMS under Accession Nos. ML20059N787 and ML20059N790, respectively. The exemption is reproduced (with the exception of abbreviated titles and additional citations) in Section II of this document. The amendment documents for COLs NPF–91 and NPF–92 are available in ADAMS under Accession Nos. ML20059N779 and ML20059N782, respectively. A summary of the amendment documents is provided in Section III of this document.

II. Exemption

Reproduced below is the exemption document issued to VEGP Units 3 and Unit 4. It makes reference to the combined safety evaluation that provides the reasoning for the findings made by the NRC (and listed under Item 1) in order to grant the exemption:

1. In a letter dated November 22, 2019, Southern Nuclear Operating Company (SNC) requested from the Nuclear Regulatory Commission (NRC or Commission) an exemption to allow departures from Tier 1 information in the certified DCD incorporated by reference in 10 CFR part 52, appendix D, ''Design Certification Rule for the AP1000 Design,'' as part of license amendment request (LAR) 19–010, ''Auxiliary Building Room Heat-up.''

For the reasons set forth in Section 3.2 of the NRC staff's Safety Evaluation, which can be found in ADAMS under Accession No. ML20059N793, the Commission finds that:

A. The exemption is authorized by law;

B. the exemption presents no undue risk to public health and safety;

C. the exemption is consistent with the common defense and security;

D. special circumstances are present in that the application of the rule in this circumstance is not necessary to serve the underlying purpose of the rule;

E. the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption; and

F. the exemption will not result in a significant decrease in the level of safety otherwise provided by the design.

2. Accordingly, SNC is granted an exemption from the certified AP1000 DCD Tier 1 information, with corresponding changes to Appendix C of the Facility Combined License, as described in the licensee's request dated November 22, 2019. This exemption is related to, and necessary for the granting of License Amendment No. 181 [and 180 for Unit 4] which is being issued concurrently with this exemption.

3. As explained in Section 5.0 of the NRC staff's Safety Evaluation (ADAMS Accession No. ML20059N793), this exemption meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(9). Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment needs to be prepared in connection with the issuance of the exemption.

4. This exemption is effective as of the date of its issuance.

III. License Amendment Request

By letter dated November 22, 2019 (ADAMS Accession No. ML19326D430), SNC requested that the NRC amend the COLs for VEGP, Units 3 and 4, COLs NPF–91 and NPF–92. The proposed amendment is described in Section I of this **Federal Register** notice.

The Commission has determined for these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or COL, as applicable, proposed no significant hazards consideration determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** on January 14, 2020 (85 FR 2158). No comments were received during the 30-day comment period.

The Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments.

IV. Conclusion

Using the reasons set forth in the combined safety evaluation, the staff granted the exemption and issued the amendment that SNC requested on May 12, 2020. The exemption and amendment were issued on May 12, 2020, as part of a combined package to SNC (ADAMS Accession No. ML20059N763).

Dated: May 22, 2020.

For the Nuclear Regulatory Commission.

Victor E. Hall,

Chief, Vogtle Project Office, Office of Nuclear Reactor Regulation.

[FR Doc. 2020–11498 Filed 5–28–20; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2020–137 and CP2020–146; MC2020–138 and CP2020–147]

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:* June 2, 2020.

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).:* MC2020–137 and CP2020–146; *Filing Title:* USPS Request to Add Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 3 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* May 22, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 *et seq.,* and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* June 2, 2020.

2. *Docket No(s).:* MC2020–138 and CP2020–147; *Filing Title:* USPS Request to Add Priority Mail Contract 617 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* May 22, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 *et seq.,* and 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* June 2, 2020.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2020–11614 Filed 5–28–20; 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 REGULATORY COMMISSION

[Docket No. C2020–1; Order No. 5519]

Complaint of Randall Ehrlich

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing an order denying a motion to expand issues in the Complaint of Randall Ehrlich v. United States Postal Service, which relates to alleged discrimination by Postal Service management in continuing a suspension of mail service due to a dog hold on the Complainant's residence. This notice informs the public of that denial.

ADDRESSES: For additional information, Order No. 5519 can be accessed electronically through the Commission's website at *https://www.prc.gov.*

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction and Procedural History
II. Motion To Expand Issues
III. Commission Analysis

I. Introduction and Procedural History

On December 23, 2019, Randall Ehrlich (Complainant) filed a complaint pursuant to 39 U.S.C. 3662(a) and 403(c) concerning an ongoing suspension of mail service to his home.[1] The Complainant alleges that the Postal Service unreasonably discriminated against him in its suspension of mail delivery to his front porch mailbox. Complaint at 13. He requests that the Commission require delivery to be restored to his front porch mailbox and that ''all discriminatory acts and omissions'' against Complainant ''cease immediately.'' *Id.* at 14. On January 13, 2020, the Postal Service filed a motion to dismiss the Complaint.[2] Complainant responded to the Motion to Dismiss on January 31, 2020.[3]

Chairman's Information Request No. 1 was issued on January 16, 2020,[4] which the Postal Service responded to on January 23, 2020.[5] Chairman's Information Request No. 2 [6] was issued February 4, 2020, to which the Postal Service responded on February 18, 2020,[7] after requesting [8] and receiving [9] an extension of time to respond. Complainant replied to the Response to CHIR No. 2 on February 24, 2020.[10]

On March 17, 2020, the Commission concluded that the Complaint raised material issues of fact, and therefore denied the Postal Service's Motion to Dismiss pursuant to 39 U.S.C. 3662(b) and 39 CFR 3030.30(a)(1).[11] Additionally, the Commission appointed a Presiding Officer to set a procedural schedule and conduct limited discovery for the purpose of determining disputed issues of fact in the case.[12] The Commission stated that the scope of the discovery proceeding would be limited only to fact-finding conducted by the Presiding Officer on specific issues of fact to resolve whether a violation of 39 U.S.C. 403 occurred, namely:

1. Whether any dogs remain at Complainant's residence that are

[1] Complaint of Randall Ehrlich, December 23, 2019 (Complaint).

[2] United States Postal Service Motion to Dismiss with Prejudice the Complaint of Randall Ehrlich, January 13, 2020 (Motion to Dismiss).

[3] Response to Motion to Dismiss, January 31, 2020 (Response).

[4] Chairman's Information Request No. 1, January 16, 2020 (CHIR No. 1).

[5] Responses of the United States Postal Service to Questions No 1–2 of Chairman's Information Request No. 1, January 23, 2020 (Response to CHIR No. 1).

[6] Chairman's Information Request No. 2, February 4, 2020 (CHIR No. 2).

[7] Response of the United States Postal Service to Questions 1–4 of Chairman's Information Request No. 2, February 18, 2020 (Response to CHIR No. 2).

[8] United States Postal Service Motion for Extension of Time to File Response to Questions 1–4 of Chairman's Information Request No. 2, February 11, 2020 (Postal Service Motion).

[9] Order Granting Motion for Extension of Time to File Responses to Chairman's Information Request No. 2, February 12, 2020 (Order No. 5425). Order No. 5425 also granted Complainant additional time to respond to the Postal Service's answers. Order No. 5425 at 2.

[10] Response to USPS's Answers to Chairman Information Request No. 2, with Third Ehrlich Declaration, February 24, 2020 (Reply to CHIR No. 2 Responses).

[11] Order Denying Postal Service Motion to Dismiss Complaint and Notice of Limited Formal Proceedings, March 17, 2020, at 7 (Order No. 5455).

[12] Order No. 5455 at 8; *see* 39 CFR 3030.21.

aggressive or could be a threat to carrier safety.

2. Whether postal management followed non-discriminatory processes in its continuance of a dog hold on Complainant's residence.

3. Whether the alternate mailbox site proposed by the Complainant was a reasonable compromise between carrier safety and Complainant's security concerns.

4. Whether the Complainant is obligated to comply with a mailbox relocation if there are no aggressive dogs remaining at his residence.

5. Whether a locked mailbox at the mailbox site approved by the Postal Service would alleviate Complainant's security concerns.

Order No. 5455 at 8.

On March 18, 2020, the Presiding Officer issued a ruling scheduling a prehearing teleconference between the parties and established initial case management procedures.[13] The prehearing teleconference was held as scheduled.[14] The Presiding Officer subsequently propounded the first set of interrogatories to the Complainant and to the Postal Service on April 16, 2020, pursuant to 39 CFR 3001.12(a), 3001.26(a), and 3001.27(a).[15] Since then, the Presiding Officer has issued several other rulings modifying the procedural schedule and setting forth additional case management procedures.[16]

II. Motion To Expand Issues

On May 13, 2020, Complainant filed a motion [17] requesting that the Commission expand the issues under consideration to include the following issues related to dog holds under the Seattle District Animal/Insect Policy (Policy):

[1.] Whether the Policy, in blanketly stating that carriers shall not deliver mail to homes where dogs are kept only behind a screen or storm door, without consideration for the dog's age, sex, size, breed composition, sterilization status, degree of training, assistance animal legal status (protection under state or federal law, such as Americans with Disabilities Act, Fair Housing Act, or Washington Law Against Discrimination), animal control complaint history, adverse designation legal status, ambulatory capability or degree of incapacitation, weight, and other factors, illegally discriminates against postal customers without air conditioning or those who simply wish to enjoy a natural breeze inside their dwelling instead or artificially cooled air, rendering its continued enforcement violative of 39 U.S.C. 403(c).

[2.] Whether the presence or supervision by the customer of the dog while behind the screen or storm door negates the foregoing Policy proscription, rendering its continued enforcement violative of 39 U.S.C. 403(c).

[3.] Whether a gate or secondary barrier behind the screen or storm door negates the foregoing Policy proscription, rendering its continued enforcement violative of 39 U.S.C. 403(c).

[4.] Whether Mr. Ehrlich's carrier, Tonya Voisine, with or without USPS condonation, has engaged in retaliatory, harassing, and destructive behavior, which constitutes unreasonable or undue discrimination against Mr. Ehrlich in the course of delivering and retrieving his mailpieces in violation of 39 U.S.C. 403(c). Motion at 2.

In support of the Motion, Complainant submitted a declaration providing statements in support of his assertion that the Policy unreasonably discriminates against dog owners without air conditioning.[18] He also reiterates his concern that the mail carrier assigned to his route would continue to ''tamper with, deface, and destroy'' his mail if she is not removed from the route. Third Declaration at 2. The Postal Service responded to the Motion on May 20, 2020.[19] The Postal Service urges that the Commission deny the Motion in its entirety. Opposition at 1. It asserts that expanding the scope of the proceeding beyond the limited issue of potential discrimination against the Complainant in the maintenance of a dog hold is contrary to the intent of Order No. 5455. *Id.* at 6. It also states that expanding the scope of issues under consideration is unnecessary because the Postal Service is taking steps to permanently restore mail delivery to the front porch mailbox at Complainant's residence. *Id.*

II. Commission Analysis

The Commission has previously stated that it lacks the jurisdiction to rule on internal postal personnel issues such as carrier assignments and disciplinary actions.[20] The Motion and supporting Third Declaration seek to reintroduce the Complainant's prayer for removal of the mail carrier assigned to his route. Given the precedent on the Commission's lack of jurisdiction, it would be inappropriate to expand the issues considered to include those over which an appropriate remedy could not be granted.

Complainant also seeks to shift the focus of the Complaint away from a dispute between the Postal Service and himself, and introduce a referendum on the Postal Service's policy writ large. The Commission found discrete material issues that it referred to the Presiding Officer for resolution after careful examination of the Complaint and responses. Moreover, the Commission notes that the parties are in the midst of ongoing discovery under the direction and supervision of the Presiding Officer in an attempt to resolve those discrete issues. The extensive procedural history of this matter as well as the discovery already underway suggest that the Commission avoid expanding the scope of the issues under consideration at this juncture. If Complainant's allegations of undue discrimination vis a vis similarly situated dog owners are proven true, then the Commission could grant the relief of ordering restoration of porch delivery to the Complainant's residence without the introduction of the additional allegations. Whether the Complainant does or does not have air conditioning or the structure of his storm door are not necessary elements in obtaining the relief sought in his claim.

Finally, the Postal Service alleges in its Opposition that it is taking steps to restore porch mailbox delivery to Complainant, thereby rendering his Motion moot. The Commission commends the Postal Service for taking steps towards resolving the issue but declines to rule on the mootness claim at this time.

It is ordered:

[13] Presiding Officer's Ruling Scheduling Prehearing Teleconference and Establishing Initial Case Management Procedures, March 18, 2020.

[14] Notice of Posting of Recording, April 17, 2020.

[15] Certificate Regarding Discovery, April 16, 2020.

[16] Presiding Officer's Ruling Establishing Procedural Schedule and Additional Case Management Procedures, April 16, 2020; Presiding Officer's Ruling Denying Request for an Indefinite Abeyance and Granting 30-Day Extension of Procedural Deadlines, April 24, 2020; Presiding Officer's Ruling Adjusting Procedural Schedule, May 8, 2020.

[17] Complainant's Motion to Expand Issues, May 13, 2020 (Motion).

[18] Third Declaration of Randall Ehrlich, May 13, 2020, at 2 (Third Declaration).

[19] United States Postal Service's Opposition to Complainant's Motion to Expand Issues, May 20, 2020 (Opposition).

[20] *See* Docket No. C2015–2, Order Granting Motion to Dismiss, July 15, 2015 (Order No. 2585); Docket No. C2019–1, Order Granting Motion to Dismiss, December 12, 2018, at 11 (Order No. 4924) (''Complainant requests several remedies related to Postal Service personnel—including the removal of a letter carrier from her route as well as initiation of disciplinary actions, including the termination of several employees. . .[t]hese actions are outside the Commission's authority to grant relief. Labor and personnel decisions are the purview of the Postal Service as the postal operator.'').

1. Complainant's Motion to Expand Issues, filed May 13, 2020, is denied.

2. The Secretary shall arrange for publication of this Order in the **Federal Register**.

By the Commission.

Erica A. Barker,

Secretary.

[FR Doc. 2020–11518 Filed 5–28–20; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* May 29, 2020.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on May 20, 2020, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 616 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2020–135, CP2020–143.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2020–11510 Filed 5–28–20; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* May 29, 2020.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on May 8, 2020, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 614 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2020–130, CP2020–137.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2020–11505 Filed 5–28–20; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* May 29, 2020.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on May 22, 2020, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 617 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2020–138, CP2020–147.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2020–11511 Filed 5–28–20; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* May 29, 2020.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on May 15, 2020, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & First-Class Package Service Contract 148 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2020–134, CP2020–142.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2020–11509 Filed 5–28–20; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* May 29, 2020.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on May 12, 2020, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & First-Class Package Service Contract 147 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2020–132, CP2020–139.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2020–11507 Filed 5–28–20; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, & First-Class Package Service Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal

Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* May 29, 2020.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on May 11, 2020, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail, & First-Class Package Service Contract 69 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2020–131, CP2020–138.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2020–11506 Filed 5–28–20; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* May 29, 2020.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on May 12, 2020, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 615 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2020–133, CP2020–140.

Sean Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2020–11508 Filed 5–28–20; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Rule 8c–1, SEC File No. 270–455, OMB Control No. 3235–0514

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for approval of extension of the previously approved collection of information provided for in Rule 8c–1 (17 CFR 240.8c–1), under the Securities Exchange Act of 1934 (''Exchange Act'') (15 U.S.C. 78a *et seq.*).

Rule 8c–1 generally prohibits a broker-dealer from using its customers' securities as collateral to finance its own trading, speculating, or underwriting transactions. More specifically, Rule 8c–1 states three main principles: (1) A broker-dealer is prohibited from commingling the securities of different customers as collateral for a loan without the consent of each customer; (2) a broker-dealer cannot commingle customers' securities with its own securities under the same pledge; and (3) a broker-dealer can only pledge its customers' securities to the extent that customers are in debt to the broker-dealer. Additionally, Rule 8c–1 requires broker-dealers to make certain written notifications to pledgees in connection with such use of customer securities as collateral.[1]

The information required by Rule 8c–1 is necessary for the execution of the Commission's mandate under the Exchange Act to prevent broker-dealers from hypothecating or arranging for the hypothecation of any securities carried for the account of any customer under certain circumstances. In addition, the information required by Rule 8c–1 provides important investor protections.

There are approximately 46 respondents as of year-end 2019 (*i.e.,* broker-dealers that conducted business with the public, filed Part II of the FOCUS Report, did not claim an exemption from the Reserve Formula computation, and reported that they had a bank loan during at least one quarter of the current year). Each respondent makes an estimated 45 annual responses, for an aggregate total of 2,070 responses per year.[2] Each response takes approximately 0.5 hours to complete. Therefore, the total third-party disclosure burden per year is 1,035 hours.[3]

The retention period for the recordkeeping requirement under Rule 8c–1 is three years. The recordkeeping requirement under Rule 8c–1 is mandatory to ensure that broker-dealers do not commingle their securities or use them to finance the broker-dealers' proprietary business. This rule does not involve the collection of confidential or personal identifiable information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to (i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: May 26 2020.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–11595 Filed 5–28–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Rule 611, SEC File No. 270–540, OMB Control No. 3235–0600

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the

[1] *See* Exchange Act Release No. 2690 (November 15, 1940); Exchange Act Release No. 9428 (December 29, 1971).

[2] 46 respondents × 45 annual responses = 2,070 aggregate total of annual responses.

[3] 2,070 responses × 0.5 hours = 1,035 hours.

Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 611 (17 CFR 242.611) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act''). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

On June 9, 2005, effective August 29, 2005 (*see* 70 FR 37496, June 29, 2005), the Commission adopted Rule 611 of Regulation NMS under the Exchange Act to require any national securities exchange, national securities association, alternative trading system, exchange market maker, over-the-counter market maker, and any other broker-dealer that executes orders internally by trading as principal or crossing orders as agent, to establish, maintain, and enforce written policies and procedures reasonably designed to prevent the execution of a transaction in its market at a price that is inferior to a bid or offer displayed in another market at the time of execution (a ''trade-though''), absent an applicable exception and, if relying on an exception, that are reasonably designed to assure compliance with the terms of the exception. Without this collection of information, respondents would not have a means to enforce compliance with the Commission's intention to prevent trade-throughs pursuant to the rule.

There are approximately 366 respondents [1] per year that will require an aggregate total of approximately 21,960 hours to comply with this Rule. It is anticipated that each respondent will continue to expend approximately 60 hours annually: Two hours per month of internal legal time and three hours per month of internal compliance time to ensure that its written policies and procedures are up-to-date and remain in compliance with Rule 611. The estimated cost for an in-house attorney is $396 per hour and the estimated cost for an assistant compliance director in the securities industry is $349 per hour. Therefore the estimated total internal cost of compliance for the annual hour burden is as follows: [(2 legal hours × 12 months × $396) × 366] + [(3 compliance hours × 12 months × $349) × 366] = $8,076,888.[2]

Written comments are invited on: (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 estimates of the burden of the proposed collection of information; (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 respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov*.

Dated: May 26, 2020.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–11594 Filed 5–28–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Rule 203–3, Form ADV–H, SEC File No. 270–481, OMB Control No. 3235–0538

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (the ''Commission'') is soliciting comments on the collection of information summarized below. The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

The title for the collection of information is ''Form ADV–H under the Investment Advisers Act of 1940.'' Rule 203–3 (17 CFR 275.203–3) under the Investment Advisers Act of 1940 (15 U.S.C. 80b) requires that registered advisers requesting either a temporary or continuing hardship exemption submit the request on Form ADV–H. Rule 204–4 (17 CFR 275.204–4) under the Investment Advisers Act of 1940 requires that exempt reporting advisers requesting a temporary hardship exemption submit the request on Form ADV–H. The purpose of this collection of information is to permit advisers to obtain a hardship exemption to not complete an electronic filing. The temporary hardship exemption that is available to registered advisers under rule 203–3 and exempt reporting advisers under rule 204–4 permits these advisers to make late filings due to unforeseen computer or software problems. The continuing hardship exemption available to registered advisers under rule 203–3 permits advisers to submit all required electronic filings on hard copy for data entry by the operator of the IARD.

The Commission has estimated that compliance with the requirement to complete Form ADV–H imposes a total burden of approximately one hour for an adviser. Based on our experience, we estimate that we will receive fifteen Form ADV–H filings annually from registered investment advisers and one Form ADV–H filing annually from exempt reporting advisers. Based on the 60 minute per respondent estimate, the Commission estimates a total annual burden of 16 hours for this collection of information.

Rule 203–3, rule 204–4, and Form ADV–H do not require recordkeeping or records retention. The collection of information requirements under the rule and form are mandatory. The information collected pursuant to the rule and Form ADV–H consists of filings with the Commission. These filings are not kept confidential. 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 control number.

Written 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 will have practical utility;

[1] This estimate includes 17 national securities exchanges that are equity securities exchanges. The estimate also includes an estimated 318 firms that are over-the-counter market makers or exchange market makers, as well as an estimated 31 alternative trading systems that trade NMS stocks.

[2] The total cost of compliance for the annual hour burden has been revised to reflect updated estimated cost figures for an in-house attorney and an assistant compliance director. These figures are from SIFMA's *Management & Professional Earnings in the Securities Industry 2017,* modified by Commission staff to account for an 1800-hour work-year and multiplied by 5.35 to account for bonuses, firm size, employee benefits, and overhead.

(b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; 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. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, C/O Cynthia Roscoe, 100 F Street NE, Washington, DC 20549; or send an email to: *PRA_Mailbox@sec.gov.*

Dated: May 26, 2020.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–11596 Filed 5–28–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:

Rule 17a–5, SEC File No. 270–155, OMB Control No. 3235–0123

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (''PRA''), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 17a–5 (17 CFR 240.17a–5), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 17a–5 is the basic financial reporting rule for brokers and dealers.[1] The rule requires the filing of Form X–17A–5, the Financial and Operational Combined Uniform Single Report (''FOCUS Report''), which was the result of years of study and comments by representatives of the securities industry through advisory committees and through the normal rule proposal methods. The FOCUS Report was designed to eliminate the overlapping regulatory reports required by various self-regulatory organizations and the Commission and to reduce reporting burdens as much as possible. The rule also requires the filing of an annual audited report of financial statements.

The FOCUS Report consists of: (1) Part I, which is a monthly report that must be filed by brokers or dealers that clear transactions or carry customer securities; (2) one of three alternative quarterly reports: Part II, which must be filed by brokers or dealers that clear transactions or carry customer securities; Part IIA, which must be filed by brokers or dealers that do not clear transactions or carry customer securities; and Part IIB, which must be filed by specialized broker-dealers registered with the Commission as OTC derivatives dealers; [2] (3) supplemental schedules, which must be filed annually; and (4) a facing page, which must be filed with the annual audited report of financial statements. Under the rule, a broker or dealer that computes certain of its capital charges in accordance with Appendix E to Exchange Act Rule 15c3–1 must file additional monthly, quarterly, and annual reports with the Commission.

The Commission estimates that the total hour burden under Rule 17a–5 is approximately 328,746 hours per year when annualized, and the total cost burden under Rule 17a–5 is approximately $35,287,127 per year.

Written comments are invited on: (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 estimate of the burden of the proposed collection of information; (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 respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or send an email to *PRA_Mailbox@sec.gov.*

Dated: May 26, 2020.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–11593 Filed 5–28–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting; Cancellation

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 85 FR 31564, May 26, 2020.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Wednesday, May 27, 2020 at 2:00 p.m.

CHANGES IN THE MEETING: The Closed Meeting scheduled for Wednesday, May 27, 2020 at 2:00 p.m., has been cancelled.

CONTACT PERSON FOR MORE INFORMATION: For further information; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Dated: May 27, 2020.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2020–11714 Filed 5–27–20; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension: Rule 15c2–5, SEC File No. 270–195; OMB Control No. 3235–0198

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for approval of extension of the previously approved collection of information provided for in Rule 15c2–5 (17 CFR 240.15c2–5), under the Securities Exchange Act of 1934 (15 U.S.C. 78 *et seq.*) (''Exchange Act'').

Rule 15c2–5 prohibits a broker-dealer from arranging or extending certain

[1] Rule 17a–5(c) requires a broker or dealer to furnish certain of its financial information to customers and is subject to a separate PRA filing (OMB Control Number 3235–0199).

[2] Part IIB of Form X–17A–5 must be filed by OTC derivatives dealers under Exchange Act Rule 17a–12 and is subject to a separate PRA filing (OMB control number 3235–0498).

loans to persons in connection with the offer or sale of securities unless, before any element of the transaction is entered into, the broker-dealer: (1) Delivers to the person a written statement containing the exact nature and extent of the person's obligations under the loan arrangement; the risks and disadvantages of the loan arrangement; and all commissions, discounts, and other remuneration received and to be received in connection with the transaction by the broker-dealer or certain related persons (unless the person receives certain materials from the lender or broker-dealer which contain the required information); and (2) obtains from the person information on the person's financial situation and needs, reasonably determines that the transaction is suitable for the person, and retains on file and makes available to the person on request a written statement setting forth the broker-dealer's basis for determining that the transaction was suitable. The collection of information required by Rule 15c2–5 is necessary to execute the Commission's mandate under the Exchange Act to prevent fraudulent, manipulative, and deceptive acts and practices by broker-dealers.

The Commission estimates that there are approximately 50 respondents that require an aggregate total of 600 hours to comply with Rule 15c2–5.[1] Each of these approximately 50 registered broker-dealers makes an estimated six annual responses, for an aggregate total of 300 responses per year.[2] Each response takes approximately two hours to complete. Thus, the total compliance burden per year is 600 burden hours.[3] The approximate internal compliance cost per hour is $63.00 for clerical labor,[4] resulting in a total internal compliance cost of $37,800.[5] These reflect internal labor costs; there are no external labor, capital, or start-up costs.

Although Rule 15c2–5 does not specify a retention period or record-keeping requirement under the rule, broker-dealers are required to preserve the records for a period no less than six years pursuant to Rule 17a–4(c). The information required under Rule 15c2–5 is necessary for broker-dealers to engage in the lending activities prescribed in the Rule. Rule 15c2–5 does not assure confidentiality for the information retained under the rule.[6]

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following website: *www.reginfo.gov* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to (i) *www.reginfo.gov/public/do/PRAMain* and (ii) David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or by sending an email to: *PRA_Mailbox@sec.gov.*

Dated: May 26, 2020.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–11592 Filed 5–28–20; 8:45 am]

BILLING CODE 8011–01–P

[1] 50 respondents × 6 responses per year × 2 hours per response = 600 hours per year.

[2] 50 respondents × 6 responses per year = 300 responses per year.

[3] 300 responses per year × 2 hours per response = 600 hours per year.

[4] Cost per hour for a clerk is from SIFMA's Office Salaries in the Securities Industry 2013, modified by Commission staff to account for an 1800-hour work-year, multiplied by 2.93 to account for bonuses, firm size, employee benefits and overhead, and adjusted by a factor of 1.0965 to account for inflation.

[5] 600 hours per year × $63.00 per hour = $37,800 per year.

[6] The records required by Rule 15c2–5 would be available only for examination purposes of the Commission staff, state securities authorities, and the self-regulatory organizations. Subject to the provisions of the Freedom of Information Act, 5 U.S.C. 552, and the Commission's rules thereunder (17 CFR 200.80(b)(4)(iii)), the Commission does not generally publish or make available information contained in any reports, summaries, analyses, letters, or memoranda arising out of, in anticipation of, or in connection with an examination or inspection of the books and records of any person or any other investigation.

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16469 and #16470; Pennsylvania Disaster Number PA–00105

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 05/22/2020.

Incident: Apartment Complex Fire.

Incident Period: 05/12/2020.

DATES: Issued on 05/22/2020.

Physical Loan Application Deadline Date: 07/21/2020.

Economic Injury (EIDL) Loan Application Deadline Date: 02/22/2021.

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: Huntingdon

Contiguous Counties:

Pennsylvania—Bedford, Blair, Centre, Franklin, Fulton, Juniata, Mifflin.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	2.500
Homeowners Without Credit Available Elsewhere	1.250
Businesses With Credit Available Elsewhere	6.000
Businesses Without Credit Available Elsewhere	3.000
Non-Profit Organizations With Credit Available Elsewhere	2.750
Non-Profit Organizations Without Credit Available Elsewhere	2.750
For Economic Injury:	
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere	3.000
Non-Profit Organizations Without Credit Available Elsewhere	2.750

The number assigned to this disaster for physical damage is 16469 5 and for economic injury is 16470 0.

The State which received an EIDL Declaration # is Pennsylvania.

(Catalog of Federal Domestic Assistance Number 59008)

Jovita Carranza,

Administrator.

[FR Doc. 2020–11550 Filed 5–28–20; 8:45 am]

BILLING CODE 8026–03–P

STATE JUSTICE INSTITUTE

SJI Board of Directors Meeting, Notice

AGENCY: State Justice Institute.

ACTION: Notice of meeting.

SUMMARY: The SJI Board of Directors will be meeting on Monday, June 29, 2020 at 1:00 p.m. ET. The purpose of this meeting is to consider grant applications for the 3rd quarter of FY 2020, and other business.

FOR FURTHER INFORMATION CONTACT: Jonathan Mattiello, Executive Director, State Justice Institute, 11951 Freedom Drive, Suite 1020, Reston, VA 20190, 571–313–8843, *contact@sji.gov.*

Jonathan D. Mattiello,

Executive Director.

[FR Doc. 2020–11517 Filed 5–28–20; 8:45 am]

BILLING CODE 6820–SC–P

SURFACE TRANSPORTATION BOARD

30-Day Notice of Intent To Seek Extension of Approval of Collection: Statutory Licensing Authority

AGENCY: Surface Transportation Board.

ACTION: Notice and request for comments.

SUMMARY: As required by the Paperwork Reduction Act of 1995 (PRA), the Surface Transportation Board (STB or Board) gives notice of its intent to seek approval from the Office of Management and Budget (OMB) for an extension of approval for the information collection required from those seeking statutory licensing authority, as described below. The Board previously published a notice about this collection in the **Federal Register** on April 17, 2020 (85 FR 21495). That notice allowed for a 60-day public review and comment period. No comments were received.

DATES: Comments on this information collection should be submitted by June 29, 2020.

ADDRESSES: Written comments should be identified as ''Paperwork Reduction Act Comments, Surface Transportation Board: Statutory Licensing Authority.'' Written comments for the proposed information collection should be submitted via *www.reginfo.gov/public/do/PRAMain*. This information collection can be accessed by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. As an alternative, written comments may be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Michael J. McManus, Surface Transportation Board Desk Officer: by email at *oira_submission@omb.eop.gov*; by fax at (202) 395–1743; or by mail to Room 10235, 725 17th Street NW, Washington, DC 20503.

Please also direct comments to Chris Oehrle, PRA Officer, Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001 and to *PRA@stb.gov*. For further information regarding this collection, contact Michael Higgins, Deputy Director, Office of Public Assistance, Governmental Affairs (OPAGAC), and Compliance, at (202) 245–0284 or *michael.higgins@stb.gov*. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: Comments are requested concerning: (1) The accuracy of the Board's burden estimates; (2) ways to enhance the quality, utility, and clarity of the information collected; (3) 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, when appropriate; and (4) whether the collection of information is necessary for the proper performance of the functions of the Board, including whether the collection has practical utility. Submitted comments will be summarized and included in the Board's request for OMB approval.

Description of Collection

Title: Statutory Licensing Authority.

OMB Control Number: 2140–0023.

STB Form Number: None.

Type of Review: Extension without change.

Respondents: Rail carriers and non-carriers seeking statutory licensing or consolidation authority, an exemption from filing an application for such authority, or interchange commitments.

Number of Respondents: 80.

Estimated Time Per Response:

ESTIMATED HOURS PER RESPONSE

Type of filing	Number of hours per response under 49 U.S.C. 10901–03 and 11323–26
Applications	524
Petitions *	58
Notices *	19
Interchange commitments	8

Frequency: On occasion.

AVERAGE ANNUAL NUMBER OF RESPONSES FOR FY 2017–2019

Type of filing	Average number of filings per year under 49 U.S.C. 10901–03 and 11323–26
Applications	3
Petitions *	12
Notices *	103
Interchange commitments	4

Total Burden Hours (*annually including all respondents*): 4,257 (sum of estimated hours per response × number of responses for each type of filing).

TOTAL ANNUAL BURDEN HOURS

Type of filing	Hours per response	Annual number of filings	Total annual burden hours
Applications	524	3	1,572
Petitions*	58	12	696
Notices *	19	103	1,957
Interchange commitments	8	4	32
Total annual burden hours			4,257

* Under section 10502, petitions for exemption and notices of exemption are permitted in lieu of an application.

Total ''Non-hour Burden'' Cost: Because Board collections are submitted electronically to the Board, there is no cost for filing with the Board. However, for some filings, respondents are sometimes required to send consultation letters to various other governmental agencies. Copies of these letters are part of an environmental and historic report

that must be filed with this collection (unless waived by the Board). Because some of these other agencies may require hard copy letters, there may be some limited mailing costs, which staff estimates in total to be approximately $1,750.

Needs and Uses: As mandated by Congress, persons seeking to construct, acquire or operate a line of railroad and railroads seeking to abandon or to discontinue operations over a line of railroad or, in the case of two or more railroads, to consolidate their interests through merger or a common-control arrangement are required to file an application for prior approval and authority with the Board. *See* 49 U.S.C. 10901–03, 11323–26. Under 49 U.S.C. 10502, persons may seek an exemption from many of the application requirements of sections 10901–03 and 11323–26 by filing with the Board a petition for exemption or notice of exemption in lieu of an application. The collection by the Board of these applications, petitions, and notices (including collection of disclosures of rail interchange commitments under 49 CFR 1121.3(d), 1150.33(h), 1150.43(h), and 1180.4(g)(4)) enables the Board to meet its statutory duty to regulate the referenced rail transactions. In cases in which the requests for authority involve agreements with interchange commitments that may limit the future interchange of traffic with third parties, certain information must be disclosed to the Board about those commitments. 49 CFR 1121.3(d), 1150.33(h), 1150.43(h), 1180.4(g)(4). The collection of this information facilitates the case-specific review of interchange commitments and enables the Board's monitoring of their usage generally.

Under the PRA, a federal agency that conducts or sponsors a collection of information must display a currently valid OMB control number. A collection of information, which is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c), includes agency requirements that persons submit reports, keep records, or provide information to the agency, third parties, or the public. Section 3507(b) of the PRA requires, concurrent with an agency's submitting a collection to OMB for approval, a 30-day notice and comment period through publication in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information.

Dated: May 26, 2020.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2020–11589 Filed 5–28–20; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

30-Day Notice of Intent To Seek Extension of Approval: Report of Fuel Cost, Consumption, and Surcharge Revenue

AGENCY: Surface Transportation Board.

ACTION: Notice and request for comments.

SUMMARY: As required by the Paperwork Reduction Act of 1995 (PRA), the Surface Transportation Board (STB or Board) gives notice of its intent to seek approval from the Office of Management and Budget (OMB) for an extension of the collection of the Report of Fuel Cost, Consumption, and Surcharge Revenue, as described below. The Board previously published a notice about this collection in the **Federal Register** on April 17, 2020 (85 FR 21496). That notice allowed for a 60-day public review and comment period. No comments were received.

DATES: Comments on this information collection should be submitted by June 29, 2020.

ADDRESSES: Written comments should be identified as ''Paperwork Reduction Act Comments, Surface Transportation Board: Report of Fuel Cost, Consumption, and Surcharge Revenue.'' Written comments for the proposed information collection should be submitted via *www.reginfo.gov/public/do/PRAMain.* This information collection can be accessed by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. As an alternative, written comments may be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Michael J. McManus, Surface Transportation Board Desk Officer: by email at *oira_submission@omb.eop.gov;* by fax at (202) 395–1743; or by mail to Room 10235, 725 17th Street NW, Washington, DC 20503.

Please also direct comments to Chris Oehrle, PRA Officer, Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001 and to *PRA@stb.gov.* For further information regarding this collection, contact Michael Higgins, Deputy Director, Office of Public Assistance, Governmental Affairs (OPAGAC), and Compliance, at (202) 245–0284 or *michael.higgins@stb.gov.* Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: Comments are requested concerning: (1) The accuracy of the Board's burden estimates; (2) ways to enhance the quality, utility, and clarity of the information collected; (3) 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, when appropriate; and (4) whether the collection of information is necessary for the proper performance of the functions of the Board, including whether the collection has practical utility. Submitted comments will be summarized and included in the Board's request for OMB approval.

Description of Collection

Title: Report of Fuel Cost, Consumption, and Surcharge Revenue.

OMB Control Number: 2140–0014.

STB Form Number: None.

Type of Review: Extension without change.

Respondents: Class I [large] railroads.

Number of Respondents: Seven.

Estimated Time per Response: One hour.

Frequency: Quarterly.

Total Burden Hours (annually including all respondents): 28.

Total ''Non-hour Burden'' Cost: None identified. Filings are submitted electronically to the Board.

Needs and Uses: Under 49 U.S.C. 10702, the Board has the authority to address the reasonableness of a rail carrier's practices. This information collection permits the Board to monitor the current fuel surcharge practices of the Class I carriers. Failure to collect this information would impede the Board's ability to fulfill its statutory responsibilities. The Board has authority to collect information about rail costs and revenues under 49 U.S.C. 11144 and 11145.

Under the PRA, a federal agency that conducts or sponsors a collection of information must display a currently valid OMB control number. A collection of information, which is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c), includes agency requirements that persons submit reports, keep records, or provide information to the agency, third parties, or the public. Section 3507(b) of the PRA requires, concurrent with an agency's submitting a collection to OMB for approval, a 30-day notice and comment period through publication in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information.

Dated: May 26, 2020.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2020–11570 Filed 5–28–20; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2020–0008]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of applications for exemption; request for comments.

SUMMARY: FMCSA announces receipt of applications from five individuals for an exemption from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) to operate a commercial motor vehicle (CMV) in interstate commerce. If granted, the exemptions will enable these individuals to operate CMVs in interstate commerce without meeting the vision requirement in one eye.

DATES: Comments must be received on or before June 29, 2020.

ADDRESSES: You may submit comments identified by the Federal Docket Management System (FDMS) Docket No. FMCSA–2020–0008 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/docket?D=FMCSA-2020-0008.* Follow the online instructions for submitting comments.
- *Mail:* Docket 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, Department of Transportation, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are 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 Docket 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–2020–0008), 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 *http://www.regulations.gov/docket?D=FMCSA-2020-0008.* Click on the ''Comment Now!'' 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 Documents and Comments

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to *http://www.regulations.gov/docket?D=FMCSA-2020-0008* and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, 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 Docket 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.dot.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 five individuals listed in this notice have requested an exemption from the vision requirement in 49 CFR 391.41(b)(10). Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting an exemption will achieve the required level of safety mandated by statute.

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 at 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 standard red, green, and amber.

On July 16, 1992, the Agency first published the criteria for the Vision Waiver Program, which listed the conditions and reporting standards that CMV drivers approved for participation would need to meet (57 FR 31458). The current Vision Exemption Program was established in 1998, following the enactment of amendments to the statutes governing exemptions made by § 4007 of the Transportation Equity Act for the 21st Century (TEA–21), Public Law 105–178, 112 Stat. 107, 401 (June 9, 1998). Vision exemptions are considered under the procedures established in 49 CFR part 381 subpart C, on a case-by-case basis upon application by CMV drivers who do not meet the vision standards of § 391.41(b)(10).

To qualify for an exemption from the vision requirement, FMCSA requires a person to present verifiable evidence that he/she has driven a commercial

vehicle safely in intrastate commerce with the vision deficiency for the past 3 years. Recent driving performance is especially important in evaluating future safety, according to several research studies designed to correlate past and future driving performance. Results of these studies support the principle that the best predictor of future performance by a driver is his/her past record of crashes and traffic violations. Copies of the studies may be found at *https://www.regulations.gov/docket?D=FMCSA-1998-3637.*

FMCSA believes it can properly apply the principle to monocular drivers, because data from the Federal Highway Administration's (FHWA) former waiver study program clearly demonstrated the driving performance of experienced monocular drivers in the program is better than that of all CMV drivers collectively.[1] The fact that experienced monocular drivers demonstrated safe driving records in the waiver program supports a conclusion that other monocular drivers, meeting the same qualifying conditions as those required by the waiver program, are also likely to have adapted to their vision deficiency and will continue to operate safely.

The first major research correlating past and future performance was done in England by Greenwood and Yule in 1920. Subsequent studies, building on that model, concluded that crash rates for the same individual exposed to certain risks for two different time periods vary only slightly (See Bates and Neyman, University of California Publications in Statistics, April 1952). Other studies demonstrated theories of predicting crash proneness from crash history coupled with other factors. These factors—such as age, sex, geographic location, mileage driven and conviction history—are used every day by insurance companies and motor vehicle bureaus to predict the probability of an individual experiencing future crashes (See Weber, Donald C., ''Accident Rate Potential: An Application of Multiple Regression Analysis of a Poisson Process,'' Journal of American Statistical Association, June 1971). A 1964 California Driver Record Study prepared by the California Department of Motor Vehicles concluded that the best overall crash predictor for both concurrent and nonconcurrent events is the number of single convictions. This study used 3 consecutive years of data, comparing the experiences of drivers in the first 2 years with their experiences in the final year.

[1] A thorough discussion of this issue may be found in a FHWA final rule published in the **Federal Register** on March 26, 1996 and available on the internet at *https://www.govinfo.gov/content/pkg/FR-1996-03-26/pdf/96-7226.pdf.*

III. Qualifications of Applicants

Thomas M. Bakeberg

Mr. Bakeberg, 30, has had a retinal detachment in his left eye since 2015. The visual acuity in his right eye is 20/20, and in his left eye, 20/80. Following an examination in 2020, his optometrist stated, ''In my medical opinion, Mr. Bakeberg has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. Bakeberg reported that he has driven straight trucks for 12 years, accumulating 120,000 miles, and tractor-trailer combinations for 12 years, accumulating 120,000 miles. He holds a Class A3 CDL from South Dakota. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Jacob T. Johnson

Mr. Johnson, 28, has a retinal detachment in his right eye due to a traumatic incident in 2012. The visual acuity in his right eye is 20/70, and in his left eye, 20/20. Following an examination in 2019, his optometrist stated, ''Jacob has sufficiant [sic] vision to operate a commercial vehicle.'' Mr. Johnson reported that he has driven straight trucks for 5 years, accumulating 50,000 miles, and tractor-trailer combinations for 5 years, accumulating 200,000 miles. He holds a Class A CDL from Iowa. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Michael E. McClain, Jr.

Mr. McClain, Jr., has had a coloboma in his left eye since birth. The visual acuity in his right eye is 20/20, and in his left eye has no light perception. Following an examination in 2019, his optometrist stated, ''In my medical opinion, Michael has sufficient vision to perform the driving tasks required to operate a commercial vehicle.'' Mr. McClain reported that he has driven straight trucks for 8 years, accumulating 128,000 miles, and tractor-trailer combinations for 8 years, accumulating 64,000 miles. He holds a class AM CDL from Pennsylvania. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

Cory A. Rand

Mr. Rand, 51, has had amblyopia in his left eye since childhood. The visual acuity in his right eye is 20/20, and in his left eye, 20/150. Following an examination in 2019, his optometrist stated, ''In my opinion, Cory Rand has sufficient and adequate vision to operate a commercial motor vehicle.'' Mr. Rand reported that he has driven straight trucks for 20 years, accumulating 800,000 miles. He holds a Class C CDL from New Hampshire. His driving record for the last 3 years shows no crashes and one conviction for moving violations in a CMV; following too closely.

Paul L. Simmons

Mr. Simmons, 40, has complete loss of vision in his left eye due to a sarcoidosis infection in 2011. The visual acuity in his right eye is 20/20, and in his left eye, no light perception. Following an examination in 2019, his optometrist stated, ''His right eye is normal, and he has demonstrated that he has sufficient vision to operate a commercial motor vehicle safely over the past ten years while having no vision in his left eye.'' Mr. Simmons reported that he has driven straight trucks for 5 years, accumulating 375,000 miles, and tractor-trailer combinations for 6 years, accumulating 1.2 million miles. He holds an operator's license from North Carolina. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

IV. Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315(b), FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. We will consider all comments and material received before the close of business on the closing date indicated under the **DATES** section of the notice.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2020–11548 Filed 5–28–20; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2020–0048]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of denials.

SUMMARY: FMCSA announces its decision to deny applications from 21 individuals who requested an exemption from the Federal Motor

Carrier Safety Regulations (FMCSRs) prohibiting persons with a clinical diagnosis of epilepsy or any other condition that is likely to cause a loss of consciousness or any loss of ability to operate a commercial motor vehicle (CMV) from operating CMVs in interstate commerce.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 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 material in the docket, contact Docket Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Documents and Comments

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to *http://www.regulations.gov/docket?D=FMCSA-2020-0048* and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting Docket Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, 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 Docket 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 21 individuals who requested an exemption from the FMCSRs prohibiting persons with a clinical diagnosis of epilepsy or any other condition that is likely to cause a loss of consciousness or any loss of ability to operate a CMV from operating CMVs in interstate commerce.

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)(8).

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. 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 the eligibility criteria, the terms and conditions for Federal exemptions, and an individualized assessment of each applicant's medical information provided by the applicant.

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)(8). Therefore, the 21 applicants in this notice have been denied exemptions from the physical qualification standards in § 391.41(b)(8).

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 21 applicants do not meet the minimum time requirement for being seizure-free, either on or off of anti-seizure medication:

Christopher Bowey (WY)
Randal Clawson (CO)
Mario Cuellar-Gutierrez (CO)
Eric DeVos (IA)
John Ellinghausen (OH)
Vitorio Garcia (CA)
Stephen Grigson (IN)
Richard Jeromchek (WA)
Vang Kie (MN)
Michael Koroll (MN)
Paul LaHue (IN)
Matthew Lee (CT)
Jonathan Nass (ID)
Daniel O'Neill (CT)
Gary Oliver (NC)
Richard Parsons (KS)
Daniel Ricker (OR)
Theresa Shannon (IL)
Mark Shurtz (WA)
Peter Stevens (NC)
Ron Vargo (NJ)

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2020–11547 Filed 5–28–20; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2020–0027–N–9]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration (FRA), U.S. Department of Transportation (DOT).

ACTION: Notice of information collection; request for comment.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA) and its implementing regulations, FRA seeks approval of the Information Collection Request (ICR) abstracted below. Before submitting this ICR to the Office of Management and Budget (OMB) for approval, FRA is soliciting public comment on specific aspects of the activities identified below.

DATES: Interested persons are invited to submit comments on or before July 28, 2020.

ADDRESSES: Submit written comments on the ICR activities by mail to either: Ms. Qiana Swayne, Information Collection Clearance Officer, Office of Railroad Policy and Development, Federal Railroad Administration, 1200 New Jersey Avenue SE, Washington, DC 20590; or Ms. Kim Toone, Information Collection Clearance Officer, Office of Administration, Office of Information Technology, Federal Railroad Administration, 1200 New Jersey Avenue SE, Washington, DC 20590. Commenters requesting FRA to acknowledge receipt of their respective comments must include a self-addressed stamped postcard stating, ''Comments on OMB Control Number 2130–0615,'' and should also include the title of the ICR. Alternatively, comments may be faxed to (202) 493–6216 or (202) 493–6497, or emailed to Ms. Swayne at *Qiana.Swayne@dot.gov,* or Ms. Toone at *Kim.Toone@dot.gov.* Please refer to the assigned OMB control number in any

correspondence submitted. FRA will summarize comments received in response to this notice in a subsequent notice and include them in its information collection submission to OMB for approval.

SUPPLEMENTARY INFORMATION: The PRA, 44 U.S.C. 3501–3520, and its implementing regulations, 5 CFR part 1320, require Federal agencies to provide 60-days' notice to the public to allow comment on information collection activities before seeking OMB approval of the activities. *See* 44 U.S.C. 3506, 3507; 5 CFR 1320.8 through 1320.12. Specifically, FRA invites interested parties to comment on the following ICR regarding: (1) Whether the information collection activities are necessary for FRA to properly execute its functions, including whether the activities will have practical utility; (2) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (3) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (4) ways for FRA to minimize the burden of information collection activities on the public, including the use of automated collection techniques or other forms of information technology. *See* 44 U.S.C. 3506(c)(2)(A); 5 CFR 1320.8(d)(1).

FRA believes that soliciting public comment may reduce the administrative and paperwork burdens associated with the collection of information that Federal regulations mandate. In summary, FRA reasons that comments received will advance three objectives: (1) Reduce reporting burdens; (2) organize information collection requirements in a ''user-friendly'' format to improve the use of such information; and (3) accurately assess the resources expended to retrieve and produce information requested. *See* 44 U.S.C. 3501.

The summary below describes the ICR that FRA will submit for OMB clearance as the PRA requires:

Title: Grants Management Requirements for Federal Railroad Administration. Grant Awards and Cooperative Agreements.

OMB Control Number: 2130–0615.

Abstract: FRA solicits grant applications for projects including, but not limited to, preconstruction planning activities, safety improvements, congestion relief, improvement of grade crossings, and rail line relocation, as well as projects that encourage development, expansion, and upgrades to passenger and freight rail infrastructure and services. FRA funds projects that meet FRA and government-wide evaluation standards and align with the DOT Strategic Plan.

FRA administers award agreements for both construction and non-construction projects that will result in benefits or other tangible improvements in rail corridors, service, safety, and technology. These projects include completion of preliminary engineering, environmental, research and development, final design, and construction.

FRA requires systematic and uniform collection and submission of information, as approved by OMB, to ensure accountability of Federal assistance provided by FRA. Through this information collection, FRA will measure Federal award recipients' performance and results, including expenditures in support of agreed-upon activities and allowable costs outlined in an FRA Notice of Grant Award. This information collection includes OMB-required reports and documentation, as well as additional forms and submissions to compile evidence relevant to addressing FRA's important policy challenges, promoting cost-effectiveness in FRA programs, and providing effective oversight of programmatic and financial performance. FRA issues and manages awards in compliance with 2 CFR part 200: Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards. The forms for which FRA is seeking renewal of its current approval are listed below. All non-research awards are subject to the application, reporting, closeout, and other processes described in this notice.

Form(s): All FRA forms are located at FRA's public website; all SF forms are located at *Grants.gov*. FRA forms 30 (FRA Assurance and Certifications Regarding Lobbying; Debarment, Suspension and Other Responsibility Matters and Drug-Free Workplace Requirements), 31 (Grant Adjustment Require Form), 32 (Service Outcome Agreement Annual Reporting), 33 (Final Performance Report), 34 (Quarterly Progress Report), 35 (Application Form), 217 (Categorical Exclusion Worksheet), 229 (NIST Manufacturing Extension Partnership Supplier Scouting—FRA Item Opportunity Synopsis), 251 (Applicant Financial Capability Questionnaire), and 252 (Payment Summary Spreadsheet). SF forms 270 (Request for Advance or Reimbursement), 424 (Application for Federal Assistance), 424 A (Budget Information for Non-Construction Programs), 424B (Assurance for Non-Construction Programs), 424C (Budget Information for Construction Programs), 424D (Assurances for Construction Programs), 425 (Federal Financial Report), and LLL (Disclosure of Lobbying Activities).

Type of Request: Revision of a currently approved collection.

Affected Public: Generally includes States and local governments and railroads.

Frequency of Submission: Varied; on occasion/monthly.

Reporting Burden:

Form name	Form	Grant activity/ process	Total annual responses	Average time (hours) per response	Total annual burden hours	Total annual dollar cost equivalent
Grant Application	FRA F 35	Application	250	34	8,500.00	$348,415.00
Application for Federal Assistance	SF 424	Application	250	1.1	275.00	11,272.25
Budget Information for Non-Construction Programs.	SF 424A	Application	75	3	225.00	9,222.75
Assurances for Non-Construction Programs.	SF 424B	Application	75	0.25	18.75	768.56
Budget Information for Construction Programs.	SF 424C	Application	175	3	525.00	21,519.75
Assurances for Construction Programs	SF 424D	Application	175	0.25	43.75	1,793.31
Disclosure of Lobbying Activities	SF LLL	Application	250	0.17	42.50	1,742.08
Applicant Financial Capability Questionnaire.	FRA F 251	Application	168	2	336.00	13,772.64

Form name	Form	Grant activity/ process	Total annual responses	Average time (hours) per response	Total annual burden hours	Total annual dollar cost equivalent
FRA Assurances and Certifications Regarding Lobbying; Debarment, Suspension and Other Responsibility Matters and Drug-Free Workplace Requirement.	FRA F 30	Application	250	0.25	62.50	2,561.88
Federal Financial Report (new awardees submit each quarter).	SF 425 *New Awards*.	Awards & Maintenance.	500	1.5	750.00	30,742.50
Federal Financial Report (existing awardees submit each quarter).	SF 425 *Existing Grantees*.	Awards & Maintenance.	864	1.5	1,296.00	53,123.04
Request for Advance or Reimbursement.	SF 270	Awards & Maintenance.	860	1	860.00	35,251.40
Payment Summary Spreadsheet	SF 252	Awards & Maintenance.	860	0.5	430.00	17,625.70
Quarterly Progress Report (new awardees submit each quarter).	FRA F 34 *New Awards*.	Awards & Maintenance.	500	2	1,000.00	40,990.00
Quarterly Progress Report (existing awardees submit each quarter).	FRA F 34 *Existing Grantees*.	Awards & Maintenance.	864	2	1,728.00	70,830.72
Grant Adjustment Request Form	FRA F 31	Awards & Maintenance.	212	1	212.00	8,689.88
Service Outcome Agreement (SOA) Annual Reporting.	FRA F 32	Awards & Maintenance.	24	1	24.00	983.76
Certification of Compliance or Non-Compliance with Buy America Requirements for Steel, Iron, or Manufactured Products being produced by Awardee.	Narrative Request.	Buy America Component.	15	3	45.00	1,844.55
Certification of Compliance with Buy America for Rolling Stock.	Narrative Request.	Buy America Component.	1	62	62.00	2,541.38
Waivers—Requests/Applications for Waivers, excluding FRA Form 229 (narrative request).	Narrative Request.	Buy America Component.	15	1200	18,000.00	737,820.00
NIST Manufacturing Extension Partnership Supplier Scouting—FRA—Item Opportunity Synopsis (FRA F 229).	FRA F 229	Buy America Component.	15	18	270.00	11,067.30
Awardee Investigations (including FRA initiated investigations).	Narrative Request.	Buy America Component.	3	333	999.00	40,949.01
Awardee direct reply to FRA after request to conduct investigation of bidder/offeror.	Narrative Request.	Buy America Component.	2	1	2.00	81.98
Additional Documents to FRA from Awardee/Investigated Party.	Narrative Request.	Buy America Component.	1	4	4.00	163.96
Transmission of Awardee/Bidder/Offeror Reply to Petitioner.	Narrative Request.	Buy America Component.	2	0.5	1.00	40.99
Awardee/Investigated Bidder/Offeror response to Petitioner Comment.	Narrative Request.	Buy America Component.	1	8	8.00	327.92
Written request to FRA for information bearing on substance of investigation which has been submitted by petitioner, interested parties, or awardees.	Narrative Request.	Buy America Component.	1	4	4.00	163.96
Detailed Statement to FRA Regarding Confidentiality of Previously Submitted Information to Agency.	Narrative Request.	Buy America Component.	1	8	8.00	327.92
Awardee Determination to make award before resolution of investigation one of this sections specified reasons.	Narrative Request.	Buy America Component.	1	40	40.00	1,639.60
Notification to FRA by Awardee to make award during pendency of investigation.	Narrative Request.	Buy America Component.	1	1	1.00	40.99
Request to FRA for Reconsideration of Initial Decision by Party Involved in Investigations.	Narrative Request.	Buy America Component.	1	80	80.00	3,279.20
Pre-Award Audit	Narrative Request.	Buy America Component.	1	33	33.00	1,352.67
Final Contract between Awardee and Bidder/Offeror.	Narrative Request.	Buy America Component.	1	16	16.00	655.84
Post Award Audit	Narrative Request.	Buy America Component.	1	256	256.00	10,493.44
Rolling Stock Domestic Content Improvement Plans.	Narrative Request.	Buy America Component.	1	120	120.00	4,918.80

Form name	Form	Grant activity/ process	Total annual responses	Average time (hours) per response	Total annual burden hours	Total annual dollar cost equivalent
Environmental Impact Statement (EIS)	Narrative Request.	Awards & Maintenance.	2	15552	31,104.00	1,274,952.96
Environmental Assessment (EA)	Narrative Request.	Awards & Maintenance.	4	3120	12,480.00	511,555.20
Categorical Exclusion Worksheet	FRA F 217	Awards & Maintenance.	50	156	7,800.00	319,722.00
Final Performance Report	FRA F 33	Closeout	79	8	632.00	25,905.68
Total			6,551.00	21,078.02	88,293.50	3,619,150.57

Total Estimated Annual Burden: 88,293.50 hours.

Total Estimated Annual Burden Hour Dollar Cost Equivalent: $3,619,150.57.

Under 44 U.S.C. 3507(a) and 5 CFR 1320.5(b) and 1320.8(b)(3)(vi), FRA informs all interested parties that it may not conduct or sponsor, and a respondent is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520.

Brett A. Jortland,

Deputy Chief Counsel.

[FR Doc. 2020–11598 Filed 5–28–20; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

Notice of Funds Availability (NOFA) Inviting Applications for the Fiscal Year (FY) 2020 Funding Round of the Capital Magnet Fund (CMF)

Funding Opportunities: Capital Magnet Fund; 2020 Funding Round.

Funding Opportunity Title: Notice of Funds Availability (NOFA) inviting Applications for the fiscal year (FY) 2020 Funding Round of the Capital Magnet Fund (CMF).

Announcement Type: Announcement of funding opportunity.

Funding Opportunity Number: CDFI–2020–CMF.

Catalog of Federal Domestic Assistance (CFDA) Number: 21.011.

Dates:

TABLE 1—FY 2020 CAPITAL MAGNET FUND FUNDING ROUND CRITICAL DEADLINES FOR APPLICANTS

Description	Deadline	Time (eastern time—ET)	Submission method
OMB Standard Form (SF)–424 Mandatory form.	June 26, 2020	11:59 p.m. ET	Electronically via *Grants.gov*.
Create AMIS Account (if Applicant doesn't have one).	July 2, 2020	11:59 p.m. ET	Electronically via Awards Management Information System (AMIS).
Last day to contact Capital Magnet Fund Staff	July 23, 2020	5:00 p.m. ET	Service Request via AMIS or CDFI Fund Helpdesk: 202–653–0421 or *cmf@cdfi.treas.gov*.
CMF Application and Required Attachments	July 27, 2020	5:00 p.m. ET	Electronically via AMIS.

Executive Summary: The Capital Magnet Fund (CMF) is administered by the Community Development Financial Institutions Fund (CDFI Fund). Through the CMF, the CDFI Fund provides financial assistance grants to Community Development Financial Institutions (CDFIs) and to qualified Nonprofit Organizations that have the development or management of affordable housing as one of their principal purposes. All awards provided through this Notice of Funds Availability (NOFA) are subject to funding availability.

I. Program Description

A. Authorizing Statute and Regulation: The CMF was established through the Housing and Economic Recovery Act of 2008 (HERA), which added section 1339 to the Federal Housing Enterprises Financial Safety and Soundness Act of 1992. For a complete understanding of the program, the CDFI Fund encourages Applicants to review the CMF interim rule (12 CFR part 1807) as amended February 8, 2016 (the CMF Interim Rule); this NOFA; the CDFI Fund's environmental quality regulation (12 CFR part 1815); the CMF funding application (referred to hereafter as the ''Application,'' meaning the application submitted in response to this NOFA); and the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR part 1000), which is the Department of the Treasury's codification of the Office of Management and Budget (OMB) government-wide framework for grants management at 2 CFR part 200 (Uniform Administrative Requirements or UAR). Each capitalized term used in this NOFA, but not defined herein, shall have the respective meanings assigned to them in the CMF Interim Rule, the Application, or the Uniform Administrative Requirements. Details regarding Application content requirements are found in the Application and related materials at *www.cdfifund.gov/cmf.*

B. History: The CDFI Fund was established by the Riegle Community Development Banking and Financial Institutions Act of 1994 to promote economic revitalization and community development through investment in and assistance to CDFIs. The CMF made its first awards in FY 2010, with subsequent funding rounds in FYs 2016, 2017, 2018, and 2019. To date, more

than $564 million has been awarded under the CMF Program.

C. Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR Part 1000): The Uniform Administrative Requirements codify financial, administrative, procurement, and program management standards that Federal award-making agencies must follow. Per the Uniform Administrative Requirements, when evaluating award Applications, awarding agencies must evaluate the risks to the program posed by each Applicant, and each Applicant's merits and eligibility. These requirements are designed to ensure that Applicants for Federal assistance receive a fair and consistent review prior to an award decision. This review will assess items such as the Applicant's financial stability, quality of management systems, history of performance, and single audit findings. In addition, the Uniform Administrative Requirements include guidance on audit requirements and other award compliance requirements for award Recipients.

D. Priorities: The purpose of the CMF is to attract private capital for and increase investment in the Development, Preservation, Rehabilitation, or Purchase of Affordable Housing for primarily Extremely Low-Income, Very Low-Income, and Low-Income Families, as well as Economic Development Activities, which, In Conjunction With Affordable Housing Activities, implement a Concerted Strategy to stabilize or revitalize a Low-Income Area or Underserved Rural Area. To pursue these objectives, the CDFI Fund has established the following priorities for the FY 2020 Funding Round: (i) Applications where at least 20 percent of all rental Affordable Housing units that will be financed and/or supported with FY 2020 CMF Awards are targeted to Very Low-Income Families and/or at least 20 percent of all Homeownership Affordable Housing units that will be financed and/or supported with FY 2020 CMF Awards are targeted to Low-Income Families; and (ii) Applications proposing to use the CMF Award to leverage private capital to finance and/or support Affordable Housing Activities and Economic Development Activities. Additionally, the CDFI Fund seeks to fund Applications serving geographically diverse Areas of Economic Distress, including Metropolitan Areas and Underserved Rural Areas. In particular, the priority for geographic diversity includes funding highly qualified Applications that serve states or territories not included in the Service Areas of Recipients in the past two CMF rounds (FY 2018 and FY 2019): Alaska, North Dakota, and South Carolina, as well as American Samoa, Guam, the Northern Mariana Islands, and the U.S. Virgin Islands.

E. Funding Limitations: The CDFI Fund reserves the right to fund, in whole or in part, any, all, or none of the Applications submitted in response to this NOFA.

II. Federal Award Information

A. Funding Availability: The CDFI Fund plans to award up to $173.8 million in grants for the CMF FY 2020 Round under this NOFA. HERA prohibits the CDFI Fund from obligating more than 15 percent of the aggregate available in CMF Awards to any Applicant, its Subsidiaries and Affiliates in the same funding round. Affiliated entities are not allowed to apply separately under this NOFA. To provide an example of the size of awards in past CMF rounds, the CDFI Fund notes that in the FY 2019 CMF Round, the statutory cap was $19.6 million, but the largest amount awarded was $7.75 million, while the average award was approximately $3.4 million. Moreover, given administrative and compliance responsibilities for Recipients, the CDFI Fund will not accept Applications for the FY 2020 Round that request less than $500,000, and will not provide awards below $500,000 to any CMF Award Recipient for the FY 2020 CMF Round. The CDFI Fund reserves the right, in its sole discretion, to provide a CMF Award in an amount other than that which the Applicant requests. However, the Award amount will not exceed the Applicant's award request as stated in its Application, nor will the Award amount be less than the Applicant's minimum Award request, if one is provided in the Application. An Applicant may receive only one Award through the FY 2020 CMF Round.

B. Types of Awards: The CDFI Fund will provide CMF Awards in the form of grants. CMF Awards must be used to support the eligible activities as set forth in 12 CFR 1807.301. A CMF Award Recipient may not distribute the CMF Award to any Affiliate, Subsidiary, or third-party entity in any manner that would create a Subrecipient relationship (as defined in the Uniform Administrative Requirements), without the CDFI Fund's prior written consent. The Recipient of a CMF Award must retain all obligations related to the Award. This restriction does not prevent a Recipient from loaning or investing directly in an Affiliate (separate legal entity) or in a specific Project being undertaken by an Affiliate.

C. Limitations on Using CMF Awards in Conjunction With Other CDFI Fund Awards/Allocations: 1. A CMF Award Recipient may not use its CMF Award for any project that also receives funding from other CDFI Fund program awards or allocations the Recipient (or any of its Affiliates) has received, except when the CMF Award dollars are used to finance/support a different ''phase'' of development in the same Project than that financed by other CDFI Fund awards or allocations. The separate phases of development financing are: (1) Predevelopment; (2) acquisition; (3) site work (preconstruction); (4) construction/rehabilitation; (5) permanent financing; or (6) bridge financing between two or more phases. This restriction does not apply to the Recipient's prior CMF Awards. The Recipient may combine its multiple CMF Awards to provide financing on any Project, including financing the same phase of any Project. However, the Recipient may not deem the same costs as Eligible Project Costs under multiple CMF Awards and must prorate the unit production performance across its multiple CMF Awards. If providing Homeownership assistance, a CMF Award may be used in conjunction with awards/allocations from other CDFI Fund programs only if the Project can be divided into such phases and the CMF Award is used in a different phase from the other CDFI Fund program awards/allocations. To clarify, a CMF Award cannot be used for a Homeownership property that is permanently financed (or supported) by both, the Recipient's (or any of its Affiliates') CMF Award, and an award/allocation from another CDFI Fund program (*e.g.,* down payment assistance funded from CMF Award may not be combined with a permanent mortgage funded from another CDFI Fund program).

2. Costs financed and/or supported by the Recipient's other awards/allocations from CDFI Fund programs, including awards from prior CMF rounds, may not be counted or reported as Leveraged Costs for the CMF Award pursuant to this NOFA, as further set forth in the Assistance Agreement. While the Recipient may combine its CMF Award pursuant to this NOFA with prior issued CMF Awards to finance/support the same Project, each CMF Award must separately meet the program requirements as outlined in the applicable Assistance Agreement and the CMF Interim Rule (12 CFR part 1807). The term ''Recipient'' includes the CMF Award Recipient and any Affiliates.

In all cases, the CMF Award remains subject to the following restriction imposed by the CDFI Bond Guarantee Program: Award funds received under any CDFI Fund program cannot be used by any participant of the CDFI Bond Guarantee Program, including Qualified Issuers, Eligible CDFIs, and Secondary Borrowers, to pay principal, interest, fees, administrative costs, or issuance costs (including Bond Issuance Fees) related to the CDFI Bond Guarantee Program, or to fund the Risk Share Pool for a Bond Issue (all capitalized terms used in this sentence, other than ''CMF Award,'' shall have the meanings ascribed to them in the CDFI Bond Guarantee Program regulations and applicable guidance).

D. Anticipated Start Date and Period of Performance: The CDFI Fund anticipates the period of performance for the FY 2020 CMF Round to begin in early 2021. The period of performance for each CMF Award begins with the date that the CDFI Fund announces the Recipients of FY 2020 CMF Awards and continues until the end of the ten-year period of affordability for all Projects financed and/or supported with the CMF Award, as set forth at 12 CFR 1807.401(d) and 12 CFR 1807.402, and as further set forth in the Assistance Agreement, during which time the Recipient must meet certain Performance Goals.

E. Eligible Activities: A CMF Award must support or finance activities that attract private capital for and increase investment in (i) the Development, Preservation, Rehabilitation, or Purchase of Affordable Housing for primarily Low-, Very Low- and Extremely Low-Income Families, and (ii) Economic Development Activities. CMF Awards may only be used as follows: (i) To provide Loan Loss Reserves, (ii) to capitalize a Revolving Loan Fund, (iii) to capitalize an Affordable Housing Fund, (iv) to capitalize a fund to support Economic Development Activities, (v) for Risk-Sharing Loans, or (vi) to provide Loan Guarantees. No more than 30 percent of a CMF Award may be used for Economic Development Activities. For the FY 2020 CMF Round, the CDFI Fund will allow all Recipients to use up to 5 percent of their CMF Award for Direct Administrative Expenses. The amount available for Direct Administrative Expenses may only be used for direct costs (as defined by the Uniform Administrative Requirements) incurred by the Recipient and related to the financing and/or support of a Project. The CDFI Fund considers the tracking of impacts and outcomes associated with Projects financed and/or supported by a CMF Award to fall under Direct Administrative Expenses. Any portion of the amount available for Direct Administrative Expenses may be used for direct costs related to the effective tracking and evaluation of program or evidence-based outcomes for Projects.

III. Eligibility Information

A. Eligible Applicants: In order to be eligible to apply for a CMF Award, an Applicant must either be a Certified CDFI or a Nonprofit Organization, as defined in 12 CFR 1807.104. Table 2 indicates the criteria that each entity type must meet in order to be eligible for a CMF Award pursuant to this NOFA. *Note:* A Certified CDFI that is also a Nonprofit Organization only needs to meet the Certified CDFI eligibility criteria described in Table 2, below, in order to be eligible for a CMF Award.

TABLE 2—APPLICANT ELIGIBILITY REQUIREMENTS

Category	Eligibility requirements
Certified CDFI	• Has been in existence as a legally formed entity for at least 3 years prior to the AMIS Application deadline under this NOFA; • Has been determined by the CDFI Fund to meet the CDFI certification requirements set forth in 12 CFR 1805.201 and as verified in the CDFI's AMIS account as of the publication date of this NOFA; and • Has not been notified in writing by the CDFI Fund that its certification has been terminated. • In cases where the CDFI Fund has provided a Certified CDFI with written notification that it no longer meets one or more certification standards and has been given an opportunity to cure, the CDFI Fund will continue to consider this Applicant to be a Certified CDFI until it has received a final determination letter that its certification has been terminated. • Has audited financial statements encompassing its two most recently completed fiscal years prior to the publication date of this NOFA.
Nonprofit Organization	• Has been in existence as a legally formed entity for at least 3 years prior to the AMIS Application deadline under this NOFA; • Meets the definition of Nonprofit Organization set forth in 12 CFR 1807.104. • Demonstrates, through articles of incorporation, by-laws, or other board-approved documents, that the development or management of affordable housing are among its principal purposes; and • Demonstrates by providing an attestation in the Application that at least thirty-three and one-third percent of its total assets are dedicated to the development or management of affordable housing. • Has audited financial statements encompassing its two most recently completed fiscal years prior to the publication date of this NOFA.
Do Not Pay	• The Do Not Pay Business Center was developed to support Federal agencies in their efforts to reduce the number of improper payments made through programs funded by the Federal government. • The CDFI Fund reserves the right, in its sole discretion, to rescind an award if the Recipient is identified as an ineligible Recipient in the Do Not Pay database.
System for Award Management (SAM)	• Each Applicant must have an active SAM registration in order to submit the required Application materials through *Grants.gov*. • SAM is a web-based, government-wide application that collects, validates, stores, and disseminates business information about the federal government's trading partners in support of the contract awards, grants, and electronic payment processes. See *SAM.gov* for more information. • Applicants must have a login.gov account to sign into SAM. Applicants must also have a DUNS number and an EIN in order to register in SAM.

TABLE 2—APPLICANT ELIGIBILITY REQUIREMENTS—Continued

Category	Eligibility requirements
	• Applicants must complete registration in SAM in order to be able to complete the *Grants.gov* registration and submit an SF–424. • The CDFI Fund reserves the right to deem an Application ineligible if the Applicant's SAM account expires during the Application evaluation period, or is set to expire before March 1, 2021, and the Applicant does not re-activate, or renew, as applicable, the account within the deadlines that the CDFI Fund communicates to affected Applicants during the Application evaluation period.
Application type and submission method through *Grants.gov* and Awards Management Information System (AMIS).	• Each Applicant must submit the required Application documents listed in Table 4. • The CDFI Fund will only accept Applications that use the official Application templates provided on the *Grants.gov* and AMIS websites. Applications submitted with alternative or altered templates will not be considered. • All Applicants must submit the required documents in two locations: (1) *Grants.gov* and (2) AMIS. ○ *Grants.gov:* Applicants must submit the Office of Management and Budget (OMB)-approved Standard Form (SF) 424 Mandatory (Application for Federal Assistance) form. ○ *AMIS:* Applicants must submit all other required Application materials. ○ All Applicants must register in the *Grants.gov* and AMIS systems to submit an Application successfully. The CDFI Fund strongly encourages Applicants to register as early as possible to meet the deadlines in Table 1. ○ *Grants.gov* and the SF–424 Mandatory form: ○ *Grants.gov* is a common website for federal agencies to post discretionary funding opportunities and for grantees to find and apply to them. ○ The SF–424 must be submitted in *Grants.gov* before the other Application materials are submitted in AMIS. Applicants are strongly encouraged to submit their SF–424 as early as possible via the *Grants.gov* portal. ○ Because the SF–424 is part of the Application, if the SF–424 is not accepted by *Grants.gov*, the CDFI Fund will not review any materials submitted in AMIS and the Application will be deemed ineligible. ○ The SF–424 must be submitted under the FY 2020 CMF Funding Opportunity Number. • AMIS: ○ AMIS is the CDFI Fund's enterprise-wide information technology system that will be used to submit and store organization and Application information with the CDFI Fund. ○ Applicants are only allowed one Capital Magnet Fund Application submission per funding round in AMIS.
Employer Identification Number (EIN)	• Each Applicant must have a unique EIN assigned by the Internal Revenue Service. • The CDFI Fund will reject an Application submitted with the EIN of a parent or Affiliate organization if that entity is not the Applicant. • The EIN of the Applicant organization in AMIS must match the EIN on the SF–424 submitted through *Grants.gov*.
DUNS number	• Pursuant to OMB guidance (68 FR 38402), each Applicant must apply using its unique DUNS number in *Grants.gov*. • The CDFI Fund will reject an Application submitted with the DUNS number of a parent or Affiliate organization. • The DUNS number of the Applicant in AMIS must match the DUNS number on the SF–424 submitted through *Grants.gov*.
AMIS Account	• Each Applicant must register as an organization in AMIS and submit all required Application materials through the AMIS portal. • If the Applicant does not fully register its organization in AMIS by the deadline set forth in Table 1, its Application will be rejected without further consideration. • The Authorized Representative must be included as a ''user'' in the Applicant's AMIS account. • An Applicant that fails to properly register and update its AMIS account may miss important communications from the CDFI Fund or not be able to successfully submit an Application.
501(c)(4) status	• Pursuant to 2 U.S.C. 1611, any 501(c)(4) organization that engages in lobbying activities is not eligible to apply for or receive a CMF Award.
Compliance with Nondiscrimination and Equal Opportunity Statutes, Regulations, and Executive Orders.	• An Applicant may not be eligible to receive an award if proceedings have been instituted against it in, by, or before any court, governmental agency, or administrative body, and a final determination, issued within the last 3 years as of the publication date of this NOFA, indicates the Applicant has violated any of the following laws: Title VI of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000d); Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794); the Age Discrimination Act of 1975 (42 U.S.C. 6101–6107); Title VIII of the Civil Rights Act of 1968, as amended (42 U.S.C. 3601 *et seq.*); and Executive Order 13166, Improving Access to Services for Persons with Limited English Proficiency.
Depository Institution Holding Company Applicant.	• In the case where a CDFI Depository Institution Holding Company Applicant intends to carry out the activities of its award through its Subsidiary CDFI Insured Depository Institution, the Application must be submitted by the CDFI Depository Institution Holding Company and reflect the activities and financial performance of the Subsidiary CDFI Insured Depository Institution.

TABLE 2—APPLICANT ELIGIBILITY REQUIREMENTS—Continued

Category	Eligibility requirements
Regulated Institutions [1]	• The Authorized Representative of the Depository Institution Holding Company Applicant must certify that the information included in the Application represents that of the Subsidiary CDFI Insured Depository Institution, and that the Award will be used to support the Subsidiary CDFI Insured Depository Institution for the eligible activities outlined in the Application. • To be eligible for an Award, each Regulated Institution Applicant must have a CAMELS/CAMEL composite rating (rating for banks and credit unions, respectively), by its Federal regulator of at least ''3.'' • Organizations with CAMELS/CAMEL composite ratings of ''4'' or ''5'' will not be eligible for awards. • Organizations with a Prompt Corrective Action directive from its regulator will not be eligible for awards. • The CDFI Fund will also evaluate material concerns identified by the Appropriate Federal Banking Agency in determining eligibility of Regulated Institution Applicants.

[1] Regulated Institutions include Insured Credit Unions, Insured Depository Institutions, State-Insured Credit Unions and Depository Institution Holding Companies.

Any Applicant that does not meet the criteria in Table 2 is ineligible to apply for a CMF Award under this NOFA. Further, Section III.B describes additional considerations applicable to prior Recipients and/or allocatees under any CDFI Fund program.

B. Prior Award Recipients: Eligibility determinations in prior funding rounds have no bearing on and do not guarantee eligibility in this round. Prior CMF Award Recipients and prior award recipients of other CDFI Fund programs are eligible to apply under this NOFA, except as noted in Table 3.

TABLE 3—ELIGIBILITY REQUIREMENTS FOR APPLICANTS WHICH ARE PRIOR AWARD/ALLOCATION RECIPIENTS

Criteria	Description
Pending resolution of noncompliance	• If an Applicant (or Affiliate of an Applicant) that is a prior recipient or allocatee under any CDFI Fund program: (i) Has demonstrated it has been in noncompliance with a previous assistance agreement, award agreement, allocation agreement, bond loan agreement, or agreement to guarantee and (ii) the CDFI Fund has yet to make a final determination as to whether the entity is in noncompliance with or default of its previous agreement, the CDFI Fund will consider the Applicant's Application under this NOFA pending full resolution, in the sole determination of the CDFI Fund, of the noncompliance.
Default or Noncompliance status	• The CDFI Fund will not consider an Application submitted by an Applicant that is a prior CDFI Fund award recipient or allocatee under any CDFI Fund program if, as of the AMIS Application deadline of this NOFA, the CDFI Fund has made a final determination in writing that such Applicant (or Affiliate of such Applicant) is in noncompliance with or default of a previously executed assistance agreement, award agreement, allocation agreement, bond loan agreement, or agreement to guarantee. • Such entities will be ineligible to apply for an Award pursuant to this NOFA if the CDFI Fund has provided written notification that such entity is ineligible to apply for or receive any future CDFI Fund awards or allocations. Such entities will be ineligible to submit an application for such time period as specified by the CDFI Fund in writing.

C. Contacting the CDFI Fund: Accordingly, Applicants that are prior Recipients and/or allocatees under any CDFI Fund program are advised to comply with requirements specified in an Assistance Agreement, allocation agreement, bond loan agreement, or agreement to guarantee, and to ensure their Affiliates are in compliance with any agreements. All outstanding reporting and compliance questions should be directed to the Office of Certification, Compliance Monitoring and Evaluation help desk by AMIS Service Requests or by telephone at (202) 653–0421; except in the case of Capital Magnet Fund reporting and compliance questions, which should be directed to the Capital Magnet Fund help desk by completing a Service Request through AMIS using ''Capital Magnet Fund'' for the Service Request program. Alternatively, the public can contact Capital Magnet Fund staff via email at *CMF@cdfi.treas.gov*. The CDFI Fund will not respond to Applicants' reporting, compliance, or disbursement telephone calls or email inquiries that are received after 5:00 p.m. ET on July 23, 2020 until after the Application deadline. The CDFI Fund will respond to technical issues related to AMIS Accounts through 5:00 p.m. ET on July 27, 2020, via AMIS Service Requests, or at *AMIS@cdfi.treas.gov,* or by telephone at (202) 653–0422.

D. Cost sharing or matching funds requirements: Not applicable.

E. *Other Eligibility Criteria:*

1. *How Affiliated Entities Can Submit an Application:* As part of the Application review process, the CDFI Fund considers whether Applicants are Affiliates, as such term is defined in 12 CFR1807.104. If an Applicant and its Affiliate(s) wish to submit an Application, they must do so through one of the Affiliated entities, in one Application; an Applicant and its Affiliates may not submit separate Applications. If Affiliates submit multiple or separate Applications, the CDFI Fund may, at its discretion, reject all such Applications received or select only one of the submitted Applications to deem eligible, assuming that Application meets all other eligibility criteria in Section III of this NOFA.

Furthermore, an Applicant that receives an award in this CMF round may not become an Affiliate of another

Applicant that receives an award in this CMF round at any time after the submission of a CMF Application under this NOFA. This requirement will also be a term and condition of the Assistance Agreement (see Application Frequently Asked Questions on the CDFI Fund's website at *http://www.cdfifund.gov/cmf* for more details).

2. An Applicant will not be eligible to receive a CMF Award if the Applicant fails to demonstrate in the Application that its CMF Award would result in Eligible Project Costs (Leveraged Costs plus those costs funded by the CMF Award) that equal at least 10 times the amount of the CMF Award. Note that no costs attributable to Direct Administrative Expenses may be considered Eligible Project Costs.

IV. Application and Submission Information

A. Address To Request Application Package: Application materials can be found on the *Grants.gov* and the CDFI Fund's website at *www.cdfifund.gov/cmf*. Applicants may request a paper version of any Application material by contacting the CDFI Fund Help Desk by email at *cmf@cdfi.treas.gov* or by phone at (202) 653–0421.

B. Content and Form of Application Submission: The CDFI Fund will post to its website, at *www.cdfifund.gov/cmf,* instructions for accessing and submitting an Application. Detailed Application content requirements are found in the Application and related guidance documents. All Applications must be prepared in English and calculations must be made in U.S. dollars. Table 4 lists the required funding Application documents for the FY 2020 CMF Round. Applicants must submit all required documents for the Application to be deemed complete. Please be aware that an Applicant that fails to submit audited financial statements for its two most recently completed fiscal years will be deemed as not having a complete Application and will be considered ineligible. The CDFI Fund reserves the right to request and review other pertinent or public information that has not been specifically requested in this NOFA or the Application. Information submitted by the Applicant that the CDFI Fund has not specifically requested will not be reviewed or considered as part of the Application. Information submitted must accurately reflect the Applicant's activities and/or its Subsidiary Insured Depository Institution, in the case where the Applicant is an Insured Depository Institution Holding Company.

TABLE 4—FUNDING APPLICATION DOCUMENTS

Application document	Submission format	Required?
Standard Form (SF) 424 Mandatory Form	Fillable PDF in *Grants.gov*	Required for all Applicants.
CMF Application	AMIS	Required for all Applicants.
Attachments to the Application		
Audited financial statements (most recent 2 fiscal years)	PDF in AMIS	Required for all Applicants.
Any management letters related to the audited financial statements (most recent 2 fiscal years).	PDF in AMIS	Required for all Applicants.
State Charter, Articles of Incorporation, or other establishing documents designating that the Applicant is a nonprofit or not-for-profit entity under the laws of the organization's State of formation.	PDF in AMIS	Required only for Applicants that are *not* Certified CDFIs.
A certification demonstrating tax exempt status from the IRS. For Applicants that are governmental instrumentalities only, and as long as all other eligibility requirements are met, the Applicant must submit a legal opinion from counsel, in form and substance acceptable to the CDFI Fund, opining that the Applicant is exempt from Federal income tax, if the Applicant does not otherwise have such determination in a document from the IRS.	PDF in AMIS	Required only for Applicants that are *not* Certified CDFIs.
Articles of incorporation, by-laws or other documents demonstrating that the Applicant has a principal purpose of managing or developing affordable housing.	PDF in AMIS	Required only for Applicants that are *not* Certified CDFIs.

The CDFI Fund has a sequential, two-step process that requires the submission of Application documents in separate systems and on separate deadlines. The SF–424 form must be submitted through *Grants.gov* and all other Application documents through the AMIS portal. The CDFI Fund will not accept Applications via email, mail, facsimile, or other forms of communication, except in extremely rare circumstances that have been pre-approved by the CDFI Fund. The separate Application deadlines for the SF–424 and all other Application materials are listed in Tables 1 and 6. Only the Authorized Representative for the Organization or Application Point of Contact designated in AMIS may submit the Application through AMIS.

Applicants are strongly encouraged to submit the SF–424 as early as possible through *Grants.gov* in order to provide sufficient time to resolve any potential submission issues. Applicants should contact *Grants.gov* directly with questions related to the registration or submission process, as the CDFI Fund does not administer the *Grants.gov* system.

The CDFI Fund strongly encourages Applicants to start the *Grants.gov* registration process as soon as possible, as it may take several weeks to complete (refer to the following link: *http://www.grants.gov/web/grants/register.html*). An Applicant that has previously registered with *Grants.gov* must verify that its registration is current and active. If an Applicant has not previously registered with *Grants.gov,* it must first successfully register in *SAM.gov,* as described in Section IV.D below.

C. Dun and Bradstreet Data Universal Numbering System (DUNS): Pursuant to the Uniform Administrative Requirements, each Applicant must provide as part of its Application submission a valid Dun & Bradstreet Data Universal Numbering System (DUNS) number. Any Applicant without a DUNS number will not be able to register in SAM or register and submit an Application in the *Grants.gov* system. Please allow sufficient time for Dun & Bradstreet to respond to inquiries and/or requests for DUNS numbers.

D. System for Award Management (SAM): Any entity applying for Federal

grants or other forms of Federal financial assistance through *Grants.gov* must be registered in SAM before submitting its Application materials through that platform. When accessing *SAM.gov,* users will be asked to create a *login.gov* user account (if they don't already have one). Going forward, users will use their *login.gov* username and password every time when logging into *SAM.gov.* The SAM registration process can take four weeks or longer to complete so Applicants are strongly encouraged to begin the registration process upon publication of this NOFA in order to avoid potential Application submission issues. An original, signed notarized letter identifying the authorized entity administrator for the entity associated with the DUNS number is required by SAM and must be mailed to the Federal Service Desk. This requirement is applicable to new entities registering in SAM, as well as existing entities with registrations being updated or renewed in SAM. Applicants that have previously completed the SAM registration process must verify that their SAM accounts are current and active.

Applicants are required to maintain a current and active SAM account at all times during which it has an active Federal award or an Application under consideration for an award by a Federal awarding agency.

The CDFI Fund will not consider any Applicant that fails to properly register or activate its SAM account and, as a result, is unable to submit its Application by the Application deadline. Applicants must contact SAM directly with questions related to registration or SAM account changes, as the CDFI Fund does not maintain this system. For more information about SAM, please visit *https://www.sam.gov* or call 866–606–8220.

TABLE 5—*Grants.gov* REGISTRATION TIMELINE SUMMARY

Step	Agency	Estimated minimum time to complete
Obtain a DUNS number	Dun & Bradstreet	One Week.*
Register in *SAM.gov*	System for Award Management (SAM)	Four Weeks.*
Register in *Grants.gov*	*Grants.gov*	One Week.**

* Applicants are advised that the stated duration are estimates only and represent minimum timeframes. Actual timeframes may take longer. The CDFI Fund will not consider any Applicant that fails to properly register or activate its SAM account, has not yet received a DUNS number, and/or fails to properly register in *Grants.gov.*

** This estimate assumes an Applicant has a DUNS number, an EIN number, and is already registered in *SAM.gov.*

E. Submission Dates and Times:

1. *Submission Deadlines:* Table 6 lists the deadlines for submission of the documents related to the FY 2020 CMF Funding Round:

TABLE 6—FY 2020 CMF DEADLINES FOR APPLICANTS

Document	Deadline	Time—eastern time (ET)	Submission method
SF–424 Mandatory form	June 26, 2020	11:59 p.m. ET	Electronically via *Grants.gov.*
Create AMIS Account (if the Applicant does not already have one)	July 2, 2020	11:59 p.m. ET	Electronically via AMIS.
CMF Application and Required Attachments	July 27, 2020	5:00 p.m. ET	Electronically via AMIS.

2. *Confirmation of Application Submission in Grants.gov and AMIS:* Applicants are required to submit the SF–424 Mandatory Form through the *Grants.gov* system under the FY 2020 Capital Magnet Fund Funding Opportunity Number (listed at the beginning of this NOFA). All other required Application materials must be submitted through the AMIS website. Application materials submitted through each system are due by the applicable deadline listed in Table 6. Applicants must submit the SF–424 by an earlier deadline than that of the other required Application materials in AMIS. If a valid SF–424 is not submitted through *Grants.gov* by the corresponding deadline, the Applicant will not be able to submit the additional Application materials in AMIS, and the Application will be deemed ineligible. Thus, Applicants are strongly encouraged to submit the SF–424 as early as possible in the *Grants.gov* portal, given that potential submission issues may impact the ability to submit a complete Application.

(a) *Grants.gov Submission Information:* Each Applicant will receive an initial email from *Grants.gov* immediately after submitting the SF–424, confirming that the submission has entered the *Grants.gov* system. This email will contain a tracking number for the submitted SF–424. Within 48 hours, the Applicant will receive a second email which will indicate if the submitted SF–424 was either successfully validated or rejected with errors. However, Applicants should not rely on the email notification from *Grants.gov* to confirm that their SF–424 was validated. Applicants are strongly encouraged to use the tracking number provided in the first email to closely monitor the status of their SF–424 by checking *Grants.gov* directly. The Application materials submitted in AMIS are not accepted by the CDFI Fund until *Grants.gov* has validated the SF–424. In the *Grants.gov* Workspace function, please note that the Application package has not been submitted if you have not received a tracking number.

(b) *AMIS Submission Information:* AMIS is a web-based portal where Applicants will directly enter their Application information and add required attachments listed in Table 4. Each Applicant must register as an organization in AMIS in order to submit the required Application materials through this portal. AMIS will verify that the Applicant provided the minimum information required to submit an Application. Applicants are responsible for the quality and accuracy of the information and attachments included in the Application submitted in AMIS. The CDFI Fund strongly encourages the Applicant to allow sufficient time to confirm the Application content, review the material

submitted, and remedy any issues prior to the Application deadline. Applicants can only submit one Application in AMIS. Upon submission, the Application will be locked and cannot be resubmitted, edited, or modified in any way. The CDFI Fund will not unlock or allow multiple AMIS Application submissions.

Prior to submission, each Application in AMIS must be signed by an Authorized Representative. An Authorized Representative is an employee or officer and has the authority to legally bind and make representations on behalf of the Applicant; consultants working on behalf of the Applicant cannot be designated as Authorized Representatives. The Applicant may include consultants as Application point(s) of contact, who will be included on any communication regarding the Application and will be able to submit the Application but cannot sign the Application. The Authorized Representative and/or Application point(s) of contact must be included as ''Contacts'' in the Applicant's AMIS account. The Authorized Representative must also be a ''user'' in AMIS. An Applicant that fails to properly register and update its AMIS account may miss important communications from the CDFI Fund or fail to submit an Application successfully. Only an Authorized Representative for the organization or an Application point of contact can submit the Application in AMIS. After submitting its Application, the Applicant will not be permitted to revise or modify its Application in any way or attempt to negotiate the terms of an Award.

3. *Multiple Application Submissions:* Applicants are only permitted to submit one complete Application. However, the CDFI Fund does not control *Grants.gov,* which does allow for multiple submissions of the SF–424. If an Applicant submits multiple SF–424 Applications in *Grants.gov,* the CDFI Fund will only review the SF–424 Application submitted in *Grants.gov* that is attached to the AMIS Application. Applicants can only submit one Application through AMIS.

4. *Late Submission:* The CDFI Fund will not accept an SF–424 submitted after the applicable *Grants.gov* or AMIS Application submitted after the AMIS Application deadline, except where the submission delay was a direct result of a Federal government administrative or technological error. This exception includes any errors associated with *Grants.gov, SAM.gov,* AMIS or any other applicable government system. Please note that this exception does not apply to errors arising from obtaining a DUNS number from Dun & Bradstreet, which is not a government entity. An Applicant unable to make timely submission of its Application due to any errors in the process of obtaining a DUNS number will not be allowed to submit its Application after the Application deadline has passed.

(a) *SF–424 Late Submission:* In cases where a Federal government administrative or technological error directly resulted in the late submission of the SF–424, the Applicant must submit a written request for acceptance of the late SF–424 submission and include documentation of the error no later than two business days after the SF–424 deadline. The CDFI Fund will not respond to requests for acceptance of late SF–424 submissions after that time period. Applicants must submit late SF–424 submission requests to the CDFI Fund via an AMIS service request to the CDFI Program with a subject line of ''Late SF–424 Submission Request.''

(b) *Application Late Submission:* In cases where a Federal government administrative or technological error directly resulted in a late submission of the Application in AMIS, the Applicant must submit a written request for acceptance of the late Application submission and include documentation of the error no later than two business days after the Application deadline. The CDFI Fund will not respond to requests for acceptance of late Application submissions after that time period. Applicants must submit late Application submission requests to the CDFI Fund via an AMIS service request to the CDFI Program with a subject line of ''Late Application Submission Request.''

5. *Intergovernmental Review:* Not Applicable.

6. *Funding Restrictions:* CMF Awards are limited by the following:

(a) A Recipient shall use CMF Award funds only for the eligible activities set forth in 12 CFR 1807.301 and as described in Section II.C and Section II.E of this NOFA and its Assistance Agreement.

(b) A Recipient may not disburse CMF Award funds to an Affiliate, Subsidiary, or any other entity in any manner that would create a Subrecipient relationship (as defined in the Uniform Administrative Requirements) without the CDFI Fund's prior written approval.

(c) CMF Award dollars shall only be paid to the Recipient.

(d) The CDFI Fund, in its sole discretion, may pay CMF Awards in amounts, or under terms and conditions, which are different from those requested by an Applicant. However, the CDFI Fund will not grant an Award in excess of the amount requested by the Applicant.

V. Application Review Information

A. Criteria: All complete and eligible Applications will be reviewed in accordance with the criteria and procedures described in the CMF Interim Rule, this NOFA, the Application guidance, and the Uniform Administrative Requirements. As part of the review process, the CDFI Fund reserves the right to contact the Applicant by telephone, email, mail, or through an on-site visit for the sole purpose of clarifying or confirming Application information at any point during the review process. The CDFI Fund reserves the right to collect such additional information from Applicants as it deems appropriate. If contacted, the Applicant must respond within the time period communicated by the CDFI Fund or its Application may be rejected. For the sake of clarity, specific Application evaluation criteria are described in the context of the overall Application review and selection process described in Section V.B. below.

B. Review and Selection Process:

The CDFI Fund will evaluate each complete and eligible Application using the multi-phase review process described in this Section. For the first two parts of the review process, the Quantitative Assessment and External Review, the Applications will be grouped into two categories: (1) Financing entities and (2) affordable housing developers/managers. Certified CDFIs will automatically be categorized as financing entities. Nonprofit Organizations will select whether they are primarily financing entities or affordable housing developers/managers. The Applications of these two groups will be evaluated on the criteria listed in this section. Where appropriate, the CDFI Fund will use different criteria in order to evaluate the financial health, capacity, and strategies of these distinct entity types. These differences are noted in the following sections and the Application Instructions.

1. *Quantitative Assessment:* Each complete and eligible Application will receive a numeric score based on the responses to quantitative questions in the Application. Applications may receive a score of up to 100 points based on the following factors outlined in Table 7.

TABLE 7—QUANTITATIVE ASSESSMENT FACTORS

Section	Points	Assessment criteria
Business and Leveraging Strategy	40	• Private leverage multiplier. • Reasonableness of projected activities based on track record. • Whether the Application is proposing to serve Alaska, North Dakota, South Carolina, American Samoa, Guam, the Northern Mariana Islands, or the U.S. Virgin Islands.
Community Impact	35	• Percent of rental housing units targeted to Very Low-Income (VLI) or below (50 percent of AMI or below). • Percent of Homeownership units targeted to Low-Income (LI) or below (80 percent of AMI or below). • Relevant track record of financing and/or supporting units targeted to VLI or LI families. • Commitment to serve Rural Areas and track record of serving these areas. • Commitment to only finance Economic Development Activities in Low-Income Areas or Underserved Rural Areas (if proposing Economic Development Activities). • Percent of housing units to be financed and/or supported in Areas of Economic Distress.
Organizational Capacity	25	• Capitalization. • Operating Performance. • Liquidity. • Audit Results.

Within the Business and Leveraging Strategy Section of the Quantitative Assessment, an Applicant will generally score more favorably to the extent it: Proposes to leverage a higher multiplier of private capital; and has a volume of projected activities supported by its track record. An Applicant will also score slightly more favorably if it is proposing to serve Alaska, North Dakota, South Carolina, American Samoa, Guam, the Northern Mariana Islands, or the U.S. Virgin Islands.

Within the Community Impact Section, an Applicant will generally score more favorably to the extent that it commits to one or more of the following: Financing and/or supporting a higher percentage of rental housing units targeted to Very Low-Income Families (if proposing to use CMF for rental housing), and/or financing and/or supporting a higher percentage of Homeownership units targeted to Low-Income Families (if proposing to use CMF for Homeownership). The Applicant will also score more favorably to the extent that it commits to: Financing and/or supporting Economic Development Activities in Low-Income Areas only (if proposing to use CMF for Economic Developments Activities), and financing and/or supporting a higher percentage of units located in Areas of Economic Distress. Areas of Economic Distress are census tracts: (a) Where at least 20 percent of households that are Very Low-Income (50 percent of AMI or below) spend more than half of their income on housing; or (b) that are designated Qualified Opportunity Zones under 26 U.S.C. 1400Z–1; or (c) that are Low-Income Housing Tax Credit Qualified Census Tracts; or (d) where greater than 20 percent of households have incomes below the poverty rate and the rental vacancy rate is at least 10 percent; or (e) where greater than 20 percent of the households have incomes below the poverty rate and the homeownership vacancy rate is at least 10 percent; or (f) are Underserved Rural Areas as defined in the CMF Interim Rule (as amended February 8, 2016; 12 CFR part 1807). The CDFI Fund will publish a dataset on its website indicating which census tracts are designated as Areas of Economic Distress for the FY 2020 Round. Additionally, Applicants will score slightly more favorably in this section if they are willing to commit to investing 10 percent or more of their CMF Award in Rural Areas. Applicants will also score slightly more favorably if they also have a track record of serving Rural Areas that support their ability to achieve this commitment. Note that while Affordable Housing Activities may occur in any Rural Area, Economic Development Activities, In Conjunction With Affordable Housing Activities, must implement a Concerted Strategy to stabilize or revitalize a Low-Income Area or Underserved Rural Area.

Within the Financial Health section, Applicants will generally score more favorably to the extent that their 3-year financial data indicate, among other things, the following: Strong capitalization; strong operating performance; strong liquidity; and that the Applicant has not had any negative findings (*e.g.* opinion other than unqualified; a ''going concern paragraph;'' repeat findings of reportable conditions; material weaknesses in internal control) in any of the three most recently completed annual audits.

Once the quantitative score is determined, Applicants in each of the two categories (financing entities and affordable housing developers/managers) will be ranked in descending order based on their quantitative review score. The top 80 percent of Applications in each category will be forwarded to the next level of review: External Review. The CDFI Fund reserves the right to forward additional Applications to the External Review phase in order to ensure that a diversity of geographies (including different states as well as Metropolitan and Rural Areas) are served by the Applicants reviewed in the External Review phase. The CDFI Fund also reserves the right to forward all Applicants to the External Review phase, regardless of the Quantitative Assessment score, if fewer than 150 CMF Applications are received.

2. *External Review:* Applications that advance from the Quantitative Assessment will be separately scored by two or more external non-Federal reviewers who are selected based on criteria that include: A professional background in affordable housing or a background in community and economic development finance with experience with affordable housing. These reviewers must complete the CDFI Fund's conflict of interest process and be approved by the CDFI Fund. Reviewers will be assigned a set number of Applications, consisting of either financing entity Applicants or affordable housing developer/manager Applicants, to review. The reviewer will provide a score for each of the

Applications assessed in accordance with the scoring criteria outlined in Section V.B.2 of this NOFA and the Application materials.

The external reviewer's evaluation will result in the Application being awarded up to 100 total points by each reviewer. These points will be distributed across three sections: Business and Leveraging Strategy (40 possible points), Community Impact (35 possible points), and Organizational Capacity (25 possible points). An Applicant's final External Review score will be a composite based on the external reviewers' evaluation and Quantitative Assessment factors. The majority of the score will be based on the external reviewers' evaluation.

(a) *Business and Leveraging Strategy (40 points):* In the Business and Leveraging Strategy section, the Applicant will address: (i) The needs of communities and persons in the areas it proposes to serve with a CMF Award and the extent to which the proposed strategy addresses these needs; (ii) the affordable housing, economic development, and financing gaps addressed by its business strategy; (iii) the projected CMF activities and track record; (iv) the role CMF plays in its project financing strategy; (v) its strategy for leveraging private capital with a CMF Award; and (vi) its strategy for leveraging its CMF Award at the Enterprise-level, through re-investments, and/or at the Project-level (as applicable).

An Applicant will generally score more favorably in the criteria evaluated by the external reviewer to the extent that it: (i) Clearly aligns its proposed CMF Award activities and products with the affordable housing needs and financing gaps it identifies; (ii) demonstrates that its strategy and activities will result in more favorable financing rates and terms; (iii) demonstrates that its projected activities are achievable based on the Applicant's strategy and track record; (iv) describes a clear process for selecting projects that have a clear need for CMF financing; (v) has a credible pipeline of projects; (vi) has a clear strategy for and track record of leveraging private capital; and (vii) has a clear strategy for and demonstrates a track record of leveraging funds at the Enterprise-level, through re-investments, and/or at the Project-level (as applicable).

(b) *Community Impact (35 points):* In the Community Impact Section, the Applicant will address: (i) The extent to which the Applicant's strategy is likely to lead to the Affordable Housing and/or Economic Development Activities impacts referenced in the Application; (ii) its strategy and track record of financing and/or supporting housing units targeted to Low-Income Families (for Homeownership) and to Very Low-Income Families (for rental); (iii) its plans for financing and/or supporting Affordable Housing in Areas of Economic Distress; (iv) its community engagement and partnerships; (v) if applicable, its strategy and track record of financing and/or supporting Economic Development Activities and how these activities fit within a Concerted Strategy and will benefit the residents of nearby Affordable Housing.

An Applicant will generally score more favorably in the criteria evaluated by the external reviewer to the extent that it: (i) Demonstrates how its business strategy will result in one or more of the Affordable Housing and/or Economic Development Activities impacts identified in the Application and the extent to which it has articulated and quantified measurements and evidence to support these impacts; (ii) demonstrates a clear and compelling strategy for financing and/or supporting housing units targeted to Low-Income Families (for Homeownership) and Very Low-Income Families (for rental); (iii) presents a strong ability and commitment to finance and/or support Affordable Housing in Areas of Economic Distress; (iv) has demonstrated community engagement or partnerships that will enhance the Applicant's ability to execute its CMF strategy, particularly working with local and state governments to reduce regulatory barriers to affordable housing; and (v) if proposing Economic Development Activities, demonstrates how its proposed Economic Development Activities fit within a Concerted Strategy and will benefit the residents of the nearby Affordable Housing.

(c) *Organizational Capacity (25 points):* In the Organizational Capacity section, the Applicant will discuss: (i) Its management team and key staff; (ii) the roles and responsibilities of those staff in managing a CMF Award; (iii) its past experience managing Federal awards (including past CMF Awards); and (iv) its financial health and lending or property portfolio (as applicable).

An Applicant will generally score more favorably in the criteria evaluated by the external reviewer to the extent that it demonstrates: (i) Strong qualifications of its key personnel with respect to their skills and experience in identifying investments, underwriting or developing similar projects (as applicable), managing a portfolio of similar activities and ensuring compliance with program requirements; (ii) success in administering prior CMF Awards, CDFI and/or other Federal program awards; (iii) strong financial health; and (iv) solid portfolio performance (as applicable).

(d) *Scoring Anomaly:* If, in the case of a particular Application, the reviewers' total External Review scores vary significantly from each other, the CDFI Fund may, in its sole discretion, obtain the evaluation and numeric scoring of an additional reviewer to determine whether the anomalous score should be replaced with the score of the additional reviewer.

3. *Internal Review:* At the conclusion of the External Review phase, the CMF Program Manager will then determine the overall number of Applications that will be initially forwarded for Internal Review. The CMF Program Manager may initially forward an amount up to the highest scoring 50% of Applications from the External Review to the Internal Review, as long as the proportion of financing entity Applications to affordable housing developer/manager Applications in the overall Application Pool is maintained. Each group of Applications (financing entities and affordable housing developers/managers) will be ranked separately based on their External Review score. Such Applications will be forwarded for Internal Review in descending order of External Review score. The forwarded Applications will be drawn from the financing entity and affordable housing developer/manager groups in proportion to each group's representation in the overall Application pool. For example, if the Applicant pool is 60 percent financing entities and 40 percent affordable housing developers/managers and the CMF Program Manager elects to forward 50 Applications to the Internal Review Phase, the highest scoring 30 Applications from the financing entity group, and the highest scoring 20 Applications from the affordable housing developers/managers group would be forwarded to Internal Review.

These forwarded Applications will constitute the highly qualified pool. During the Internal Review, CDFI Fund staff will prioritize the Applications in the highly qualified pool for an Award based on a combination of the following criteria: (i) Final External Review score; (ii) alignment with CMF statutory and policy priorities; (iii) the overall quality of the Applicant's strategy; and (iv) the Applicant's organizational capacity and financial health. The CDFI Fund will not attempt to ensure any specific balance of financing entities and affordable housing developers/managers in the final Award pool.

In assessing the Application's alignment with CMF statutory and policy priorities, CDFI Fund staff will consider the following factors, including, but not limited to: The Applicant's proposed activities in Areas of Economic Distress; income targeting of the portfolio of Affordable Housing units to be financed and/or supported; the number of Very Low-Income rental housing units and/or Low-Income Homeownership units to be financed and/or supported; the amount of private capital it will leverage relative to the CMF Award; and the amount of new Enterprise-Level private capital that the Applicant will attract.

In assessing the quality of the Applicant's strategy, the CDFI Fund staff will consider the following factors, including, but not limited to: (i) The quality of the Applicant's strategy with respect to how the strategy and financing activities address identified community needs; (ii) whether the proposed financing activities will help to fill the financing gaps in their market; (iii) whether the CMF funds will contribute to the Applicant offering more favorable rates and terms than are currently available in its Service Area; (iv) whether the Applicant's projections are supported by its organizational track record, as well as the quality of its pipeline; (v) whether the proposed deployment/redeployment schedule is realistic, achievable and risk has been appropriately considered; (vi) the likely success of the strategy to leverage private capital; (vii) whether the strategy is adaptable to changing market conditions; (viii) whether the Applicant's strategy is likely to create identified community impacts and the extent to which the Applicant has articulated quantifiable measurements and evidence to support these impacts; (ix) the Applicant's approach for financing and/or supporting Affordable Housing in Areas of Economic Distress and meeting Affordable Housing income targeting goals; (x) to the extent the Applicant is proposing to undertake Economic Development Activities, how those activities are part of a Concerted Strategy and will benefit residents of affordable housing.

In assessing the Applicant's organizational capacity and financial health, the CDFI Fund Staff will consider the following factors, including, but not limited to, the Applicant's: Financial position and organizational strength; track record of performance and compliance with Federal awards, including all CDFI Fund awards, if applicable; ability to meet Federal award management standards and file appropriate reports and address findings from audits, including any Federal Single Audits; and staff capacity. The CDFI Fund will also review OMB-designated repositories of government-wide eligibility qualification and financial integrity information, as part of the assessment of organizational capacity.

In the case of an Applicant that has received awards from other Federal programs, the CDFI Fund reserves the right to contact officials from the appropriate Federal agency or agencies to determine whether the Recipient is in compliance with current or prior award agreements, as well as to review the results of any Federal Single Audit, and to take such information into consideration before making a CMF Award.

In addition to the criteria outlined above, the Applicant's ability to deploy the CMF Award in a timely manner will be a key determinant in funding recommendation. Deployment considerations may include the Applicant's track record of activities compared with projections, the Applicant's progress in committing and/or deploying past CMF Awards, and whether the Applicant received a FY 2020 CDFI/NACA Program award for a similar business strategy as the proposed use of the CMF Award. The CDFI Fund may also consider the number of geographies served when determining funding recommendations.

4. *Selection:* Once Applications have been internally evaluated and preliminary award determinations have been made, the Applications will be forwarded to a selecting official for a final award determination. After preliminary award determinations are made, the selecting official will review the list of potential Recipients to determine whether the Recipient pool meets the following statutory objectives:

(a) The potential Recipients' proposed Service Areas collectively represent broad geographic coverage throughout the United States; and

(b) The potential Recipients' proposed activities equitably represent both Metropolitan Areas and Rural Areas. For the purposes of the FY 2020 CMF Round, the term Rural Areas is defined per 12 CFR 1282.1 (Enterprise Duty To Serve Final Rule) as (i) A census tract outside of a Metropolitan Statistical Area as designated by the Office of Management and Budget; or (ii) A census tract in a Metropolitan Statistical Area as designated by the Office of Management and Budget that is outside of the Metropolitan Statistical Area's Urbanized Areas, as designated by the U.S. Department of Agriculture's (USDA) Rural-Urban Commuting Area (RUCA) Code #1, and outside of tracts with a housing density of over 64 housing units per square mile for USDA's RUCA Code #2. The CDFI Fund will publish a dataset indicating which census tracts are designated as Rural Areas for the FY 2020 Round on its website.

In the event the preliminary Recipient pool does not reflect the geographic coverage or representation of Metropolitan and Rural Areas present in the overall Applicant pool, the CDFI Fund reserves the right to modify CMF Award amounts and/or the CMF Recipient pool if deemed necessary to achieve either of these statutory objectives. For the purposes of conducting this analysis, the CDFI Fund will classify Applications as addressing Rural Areas if they propose to use 20% or more of their award in Rural Areas, and as addressing Metropolitan Areas if they propose to use less than 20% of their Award in Rural Areas. In order to evaluate the geographic coverage of the potential CMF Recipient pool, Applicants will be asked to designate one of the following two Service Area types in their Applications: Statewide or Multi-State. These Service Area types are further defined in the Application. The smallest Service Area an Applicant can request is one state; the largest Service Area an Applicant can propose is a 15 state Multi-State Service Area. Applicants should indicate in the narrative portions of their Application if they plan to concentrate their CMF activities in a subset (*e.g.* a county or a Metropolitan Area) of their broader Service Area. If necessary to achieve proportional activity in Rural Areas and/or broader geographic coverage, the CDFI Fund may award Applications not in the preliminary Recipient pool, including Applications outside of the highly qualified pool, in the order of their Internal Review scoring ranking. However, the CDFI Fund will not award an Application that scores in the bottom 50 percent of the External Review score rankings. During the selection process, the CDFI Fund also reserves the right to modify or place restrictions on the Service Area requested in any Applicant's Application in order to further these statutory objectives.

In cases where the selecting official's award determination varies significantly from the initial CMF Award amount recommended by the CDFI Fund staff review, the CMF Award recommendation will be forwarded to a reviewing official for final determination. The CDFI Fund, in its sole discretion, reserves the right to reject an Application and/or adjust CMF Award amounts as appropriate, based

on information obtained during the review process.

5. *Insured Depository Institution Applicants:* In the case of Applicants that are Insured Depository Institutions or Insured Credit Unions, the CDFI Fund will consider safety and soundness information from the Appropriate Federal Banking Agency or Appropriate State Agency, as applicable. If the Applicant is a CDFI Depository Institution Holding Company, the CDFI Fund will consider information provided by the Appropriate Federal Banking Agency and Appropriate State Agency about both the CDFI Depository Institution Holding Company and the CDFI Insured Depository Institution that will expend and carry out the Award. If the Appropriate Federal Banking Agency or Appropriate State Agency identifies safety and soundness concerns, the CDFI Fund will assess whether the concerns cause or will cause the Applicant to be incapable of undertaking the activities for which funding has been requested.

6. *Right of Rejection:* The CDFI Fund reserves the right to reject an Application if information (including administrative errors) comes to the attention of the CDFI Fund that adversely affects an Applicant's eligibility for an Award, adversely affects the CDFI Fund's evaluation or scoring of an Application, or indicates fraud or mismanagement on the Applicant's part, including mismanagement of another Federal award. If the CDFI Fund determines that any portion of the Application is incorrect in any material respect, the CDFI Fund reserves the right, in its sole discretion, to reject the Application. The CDFI Fund reserves the right to change its eligibility and evaluation criteria and procedures, if the CDFI Fund deems it appropriate. If said changes materially affect the CDFI Fund's Award decisions, the CDFI Fund will provide information regarding the changes through the CDFI Fund's website. There is no right to appeal the CDFI Fund's Award decisions. The CDFI Fund's Award decisions are final.

7. *Anticipated Award Announcement:* The CDFI Fund anticipates making CMF Award announcements in early 2021.

VI. Federal Award Administration Information

A. Award Notification: Each successful Applicant will receive notification from the CDFI Fund stating that its Application has been approved for an Award. Each Applicant not selected for an Award will receive notification and be provided a debriefing document in its AMIS account.

B. Administrative and Policy Requirements Prior to Entering into an Assistance Agreement: The CDFI Fund may, in its discretion and without advance notice to the Recipient, terminate the Award or take other actions as it deems appropriate if, prior to entering into an Assistance Agreement, information (including an administrative error) comes to the CDFI Fund's attention that adversely affects the following: The Recipient's eligibility for an Award; the CDFI Fund's evaluation of the Application; the Recipient's compliance with any requirement listed in the Uniform Requirements; or indicates fraud or mismanagement on the Recipient's part, including mismanagement of another Federal award.

If the Recipient's certification status as a CDFI changes prior to entering into an Assistance Agreement, the CDFI Fund reserves the right, in its sole discretion, to re-calculate the CMF Award, or modify the Assistance Agreement based on the Recipient's non-CDFI status.

By receiving notification of a CMF Award, the Recipient agrees that, if the CDFI Fund becomes aware of any information (including an administrative error) prior to the Effective Date of the Assistance Agreement that either adversely affects the Recipient's eligibility for an CMF Award, or adversely affects the CDFI Fund's evaluation of the Recipient's Application, or indicates fraud or mismanagement on the part of the Recipient, the CDFI Fund may, in its discretion and without advance notice to the Recipient, rescind the notice of award or take other actions as it deems appropriate.

The CDFI Fund reserves the right, in its sole discretion, to rescind an Award if the Recipient fails to return the Assistance Agreement, signed by an Authorized Representative of the Recipient, and/or provide the CDFI Fund with any other requested documentation, within the CDFI Fund's deadlines.

In addition, the CDFI Fund reserves the right, in its sole discretion, to terminate and rescind the Assistance Agreement and the award made under this NOFA for any criteria described in Table 8:

TABLE 8—REQUIREMENTS PRIOR TO EXECUTING AN ASSISTANCE AGREEMENT

Requirement	Criteria
Failure to meet reporting requirements	• If an Applicant received a prior award or allocation under any CDFI Fund program and is not current on the reporting requirements set forth in the previously executed assistance, award, allocation, bond loan agreement(s), or agreement to guarantee, as of the date of the notice of award, the CDFI Fund reserves the right, in its sole discretion, to delay entering into an Assistance Agreement and/or to delay making a Payment of CMF Award, until said prior Recipient or allocatee is current on the reporting requirements in the previously executed assistance, award, allocation, bond loan agreement(s), or agreement to guarantee. • If such a prior Recipient or allocatee is unable to meet this requirement within the timeframe set by the CDFI Fund, the CDFI Fund reserves the right, in its sole discretion, to terminate and rescind the notice of award and the CMF Award made under this NOFA. • Please note that automated systems employed by the CDFI Fund for receipt of reports submitted electronically typically acknowledge only a report's receipt; such acknowledgment does not warrant that the report received was complete, nor that it met reporting requirements. If said prior Recipient or allocatee is unable to meet this requirement within the timeframe set by the CDFI Fund, the CDFI Fund reserves the right, in its sole discretion, to terminate and rescind the notice of Award and the CMF Award made under this NOFA.
Failure to maintain CDFI Certification (if applicable) or eligible Nonprofit Organization status (if applicable).	• A Recipient must be a Certified CDFI or an eligible Nonprofit Organization, as each is defined in the CMF Interim Rule and this NOFA, prior to entering into an Assistance Agreement.

TABLE 8—REQUIREMENTS PRIOR TO EXECUTING AN ASSISTANCE AGREEMENT—Continued

Requirement	Criteria
	• If, at any time prior to entering into an Assistance Agreement under this NOFA, an Applicant that is a Certified CDFI has submitted reports (or failed to submit an annual certification report as instructed by the CDFI Fund) to the CDFI Fund that demonstrate noncompliance with the requirements for certification, but the CDFI Fund has yet to make a final determination regarding whether or not the entity is Certified, the CDFI Fund reserves the right, in its sole discretion, to delay entering into an Assistance Agreement and/or to delay making a Payment of CMF Award, pending full resolution, in the sole determination of the CDFI Fund, of the noncompliance. • If the Applicant is unable to meet this requirement, in the sole determination of the CDFI Fund, the CDFI Fund reserves the right, in its sole discretion, to terminate and rescind the notice of award and the CMF Award made under this NOFA.
Pending resolution of noncompliance	• The CDFI Fund will delay entering into an Assistance Agreement with a Recipient that has pending noncompliance issues with any of its previously executed CDFI Fund award(s), allocation(s), bond loan agreement(s), or agreement(s) to guarantee. • If said prior Recipient or allocatee is unable satisfactorily resolve the compliance issues, the CDFI Fund reserves the right, in its sole discretion, to terminate and rescind the notice of award and the CMF Award made under this NOFA.
Default or Noncompliance status	• If, at any time prior to entering into an Assistance Agreement, the CDFI Fund determines that an Applicant (or an Affiliate of the Applicant) that is a prior CDFI Fund Recipient or allocatee under any CDFI Fund program is noncompliant or found in default with any previously executed CDFI Fund award or Assistance agreement(s) and the CDFI Fund has provided written notification that the Applicant is ineligible to apply for or receive any future awards or allocations for a time period specified by the CDFI Fund in writing, the CDFI Fund may, in its sole discretion, delay entering into an Assistance Agreement with Applicant until the Recipient has cured the noncompliance by taking actions the CDFI Fund has specified in writing within such specified timeframe. If the Recipient is unable to cure the noncompliance within the specified timeframe, the CDFI Fund may modify or rescind all or a portion of the CMF Award made under this NOFA.
Compliance with Federal civil rights requirements.	• The CDFI Fund will terminate and rescind the Assistance Agreement and the CMF Award made under this NOFA if, prior to entering into an Assistance Agreement under this NOFA, the Recipient receives a final determination, made within the last 3 years of the publication date of this NOFA, in any proceeding instituted against the Recipient in, by, or before any court, governmental, or administrative body or agency, declaring that the CMF Award Recipient has violated the following laws: Title VI of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000d); Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794); the Age Discrimination Act of 1975 (42 U.S.C. 6101–6107); Title VIII of the Civil Rights Act of 1968, as amended (42 U.S.C. 3601 *et seq.*); and Executive Order 13166, Improving Access to Services for Persons with Limited English Proficiency.
Do Not Pay	• The CDFI Fund reserves the right, in its sole discretion, to rescind an award if the Recipient is identified as an ineligible Recipient in the Do Not Pay database. • The Do Not Pay Business Center was developed to support Federal agencies in their efforts to reduce the number of improper payments made through programs funded by the Federal government.
Safety and soundness	• If it is determined that the Recipient is or will be incapable of meeting its CMF Award obligations, the CDFI Fund will deem the Recipient to be ineligible or require it to improve safety and soundness conditions prior to entering into an Assistance Agreement.

C. Assistance Agreement: Each Applicant that is selected to receive an award under this NOFA must enter into an Assistance Agreement with the CDFI Fund in order to become a Recipient and receive Payment. Each CMF Award under this NOFA generally will have a period of performance that begins with the announcement date of the Award and continues until the end of the period of affordability, as set forth at 12 CFR 1807.401(d) and 12 CFR 1807.402, and as further set forth in the Assistance Agreement.

1. The Assistance Agreement will set forth certain required terms and conditions of the CMF Award, which will include, but not be limited to:

(a) The amount of the award;

(b) The approved uses of the award;

(c) The approved Service Area in which the award may be used;

(d) Performance goals and measures;

(e) Reinvestment requirements for Program Income; and

(f) Reporting requirements for all Recipients.

2. Prior to executing the Assistance Agreement, the CDFI Fund may, in its discretion, allow Recipients to request changes to the Service Area of the Award and certain performance goals and measures. The CDFI Fund, in its sole determination, may approve or reject these requested changes or propose other modifications, including a reduction in the Award amount. The CDFI Fund will only approve performance goals and measures or Service Area changes if it determines that such requested changes do not undermine the competitive process upon which the CMF Award determination was made. The CDFI Fund may also, in its discretion, provide Recipients the opportunity to add states to their Service Area in order to serve states not already covered in the Award pool and to further HERA's goal that the CMF serve geographically diverse areas of every state. The CDFI Fund may also, in its discretion, provide Recipients the opportunity to add states to its approved Service Area in order to serve geographies for which: (i) The President issued a ''major disaster declaration'' and (ii) the major disaster declaration makes such geographies eligible for both ''individual and public assistance.'' The major disaster declaration must be made after the publication date of this NOFA

and prior to the execution of the Recipient's Assistance Agreement. In these cases, the CDFI Fund may allow a Recipient to exceed the maximum 15 state Service Area, if applicable. Any modifications agreed upon prior to the execution of the Assistance Agreement will become a condition of the Award.

3. The Assistance Agreement shall provide that, prior to any determination by the CDFI Fund that a Recipient has failed to comply substantially with the Act, the CMF Interim Rule, or the environmental quality regulations, the CDFI Fund shall provide the Recipient with reasonable notice and opportunity for hearing. If the Recipient fails to comply substantially with the Assistance Agreement, the CDFI Fund may:

(a) Require changes in the performance goals set forth in the Assistance Agreement;

(b) Reduce or terminate the CMF Award; or

(c) Require repayment of any CMF Award that has been distributed to the Recipient.

4. The Assistance Agreement shall also provide that, if the CDFI Fund determines noncompliance with the terms and conditions of the Assistance Agreement on the part of the Recipient, the CDFI Fund may:

(a) Bar the Recipient from reapplying for any assistance from the CDFI Fund; or

(b) Take such other actions as the CDFI Fund deems appropriate or as set forth in the Assistance Agreement.

5. In addition to entering into an Assistance Agreement, each Applicant selected to receive a CMF Award must furnish to the CDFI Fund a certificate of good standing from the jurisdiction in which it was formed. The CDFI Fund may, in its sole discretion, also require the Applicant to furnish an opinion from its legal counsel, the content of which may be further specified in the Assistance Agreement, and which, among other matters, opines that:

(a) The Recipient is duly formed and in good standing in the jurisdiction in which it was formed and the jurisdiction(s) in which it transacts business;

(b) The Recipient has the authority to enter into the Assistance Agreement and undertake the activities that are specified therein;

(c) The Recipient has no pending or threatened litigation that would materially affect its ability to enter into and carry out the activities specified in the Assistance Agreement;

(d) The Recipient is not in default of its articles of incorporation or formation, bylaws or operating agreements, other organizational or establishing documents, or any agreements with the Federal government;

(e) The CMF affordability restrictions that are to be imposed by deed restrictions, covenants running with the land, or other CDFI Fund approved mechanisms are recordable and enforceable under the laws of the State and locality where the Recipient will undertake its CMF activities;

(f) The Recipient is exempt from Federal Income taxation pursuant to the Internal Revenue Code of 1986; and

(g) The Recipient is designated as a nonprofit or not for profit entity under the laws of the organization's State of formation.

D. Paperwork Reduction Act: Under the Paperwork Reduction Act (44 U.S.C. chapter 35), an agency may not conduct or sponsor a collection of information, and an individual is not required to respond to a collection of information, unless it displays a valid OMB control number. If applicable, the CDFI Fund may inform Applicants that they do not need to provide certain Application information otherwise required. Pursuant to the Paperwork Reduction Act, the Capital Magnet Fund Application has been assigned the following control number: 1559–0036.

E. Reporting: The CDFI Fund will require each Recipient that receives a CMF Award through this NOFA to account for and report to the CDFI Fund on the use of the CMF Award. This will require Recipients to establish administrative controls, subject to the Uniform Administrative Requirements and other applicable OMB guidance. The CDFI Fund will collect information from each such Recipient on its use of the CMF Award annually following Payment and more often if deemed appropriate by the CDFI Fund in its sole discretion. The CDFI Fund will provide guidance to Recipients outlining the format and content of the information required to be provided to describe how the funds were used.

The CDFI Fund may collect information from each Recipient including, but not limited to, an annual report with the components listed in Table 9:

TABLE 9—REPORTING REQUIREMENTS

Criteria	Description
Single Audit (if applicable)	A non-profit Recipient must complete an annual Single Audit pursuant to the Uniform Requirements (2 CFR 200.500) if it expends $750,000 or more in Federal awards in its fiscal year, or such other dollar threshold established by OMB pursuant to 2 CFR 200.500. If a Single Audit is required, it must be submitted electronically to the Federal Audit Clearinghouse (FAC) (see 2 CFR subpart F—Audit Requirements in the Uniform Requirements) and optionally through AMIS.
Financial Statement Audit	For-profit and nonprofit Recipients must submit a Financial Statement Audit (FSA) report in AMIS, along with the Recipient's statement of financial condition audited or reviewed by an independent certified public accountant.
Performance Report	The Recipient must submit a performance report not less than annually, which is a progress report on the Recipient's use of the CMF Award towards meeting its performance goals, Affordable Housing outcomes, and the Recipient's overall performance. The CMF Performance Report covers the Announcement Date through the Investment Period for the CMF Award and the ten-year Affordability Period for each Project. The Investment Period shall mean the period beginning with the Effective Date of the Assistance Agreement and ending not earlier than the fifth year anniversary of the Effective Date, or as otherwise established in the Assistance Agreement. The Affordability Period shall mean, for each Project, the period beginning on the date when the Project is placed into service and consisting of the full ten consecutive years thereafter, or as otherwise established in the Assistance Agreement.
	If the Recipient fails to meet a performance goal or reporting requirements, it must submit an explanation of noncompliance via AMIS.

TABLE 9—REPORTING REQUIREMENTS—Continued

Criteria	Description
Environmental Review	The Recipient shall submit the Environmental Review Notification Report each time the Recipient identifies a new proposed CMF project for which (i) a categorical exclusion does not apply and/or (ii) the Recipient determines that the proposed project does involve actions that normally require an Environmental Impact Statement, as described in 12 CFR part 1815. The Environmental Review Notification Report must be submitted to the CDFI Fund no later than one hundred eighty (180) days prior to the date that funds are Committed to a Project.

* Personally Identifiable Information (PII) is information, which if lost, compromised, or disclosed without authorization, could result in substantial harm, embarrassment, inconvenience, or unfairness to an individual. Although Applicants are required to enter addresses of homes and other properties in AMIS, Applicants should *not* include the following PII for the individuals who received the financial products or services in AMIS or in the supporting documentation (*i.e.*—name of the individual, Social Security Number, driver's license or state identification number, passport number, Alien Registration Number, etc.). *This information should be redacted from all supporting documentation (if applicable).*

Each Recipient is responsible for the timely and complete submission of the annual reporting documents. The CDFI Fund will use such information to monitor each Recipient's compliance with the requirements set forth in the Assistance Agreement and to assess the impact of the CMF. The CDFI Fund reserves the right, in its sole discretion, to modify these reporting requirements if it determines it to be appropriate and necessary; however, such reporting requirements will be modified only after notice to Recipients.

F. Financial Management and Accounting: The CDFI Fund will require Recipients to maintain financial management and accounting systems that comply with Federal statutes, regulations, and the terms and conditions of the CMF Award. These systems must be sufficient to permit the preparation of reports required by general and program specific terms and conditions, including the tracing of funds to a level of expenditures adequate to establish that such funds have been used in accordance with the Federal statutes, regulations, and the terms and conditions of the CMF Award.

The cost principles used by Recipients must be consistent with Federal cost principles; must support the accumulation of costs as required by the principles; and must provide for adequate documentation to support costs charged to the CMF Award. In addition, the CDFI Fund will require Recipients to: Maintain effective internal controls; comply with applicable statutes and regulations, the Assistance Agreement, and related guidance; evaluate and monitor compliance; take action when not in compliance; and safeguard personally identifiable information.

VII. Agency Contacts

A. Availability: The CDFI Fund will respond to questions and provide support concerning this NOFA and the Application between the hours of 9:00 a.m. and 5:00 p.m. ET, starting on the date of the publication of this NOFA until the close of business on the third business day preceding the Application deadline. The CDFI Fund will not respond to questions or provide support concerning the Application that are received after 5:00 p.m. ET on said date, until after the Application deadline. CDFI Fund IT support will be available until 5:00 p.m. ET on date of the Application deadline. Applications and other information regarding the CDFI Fund and its programs may be obtained from the CDFI Fund's website at *http://www.cdfifund.gov/cmf*. The CDFI Fund will post on its website responses to questions of general applicability regarding the CMF.

B. The CDFI Fund's contact information is listed in Table 10:

TABLE 10—CONTACT INFORMATION

Type of question	Preferred method	Telephone number (not toll free)	Email addresses
CMF	Submit a Service Request in AMIS	202–653–0421	*cmf@cdfi.treas.gov*.
CDFI Certification	Submit a Service Request in AMIS	202–653–0423	*ccme@cdfi.treas.gov*.
Compliance Monitoring and Evaluation	Submit a Service Request in AMIS	202–653–0423	*ccme@cdfi.treas.gov*.
Information Technology Support	Submit a Service Request in AMIS	202–653–0422	*AMIS@cdfi.treas.gov*.

The preferred method of contact is to submit a Service Request within AMIS. For a CMF Application question, select ''Capital Magnet Fund'' for the program. For a CDFI Certification question, select ''Certification.'' For a Compliance question, select ''Compliance & Reporting.'' For Information Technology, select ''Technical Issues.'' Failure to select the appropriate program for the Service Request could result in delays in responding to your question.

C. Communication With the CDFI Fund: The CDFI Fund will use AMIS to communicate with Applicants and Recipients, using the contact information maintained in their respective AMIS accounts. Therefore, the Recipient and any Subsidiaries, signatories, and Affiliates must maintain accurate contact information (including contact persons and Authorized Representatives, email addresses, fax numbers, phone numbers, and office addresses) in its AMIS account(s). For more information about AMIS please see the Help documents posted at *https://amis.cdfifund.gov/s/Training*.

D. Civil Rights and Diversity: Any person who is eligible to receive benefits or services from the CDFI Fund or Recipients under any of its programs is entitled to those benefits or services without being subject to prohibited discrimination. The Department of the Treasury's Office of Civil Rights and Diversity enforces various Federal statutes and regulations that prohibit discrimination in financially assisted and conducted programs and activities

of the CDFI Fund. If a person believes that s/he has been subjected to discrimination and/or reprisal because of membership in a protected group, s/he may file a complaint with: Associate Chief Human Capital Officer, Office of Civil Rights, and Diversity, 1500 Pennsylvania Ave. NW., Washington, DC 20220 or (202) 622–1160 (not a toll-free number).

E. Statutory and National Policy Requirements: The CDFI Fund will manage and administer the Federal award in a manner so as to ensure that Federal funding is expended and associated programs are implemented in full accordance with the U.S. Constitution, Federal Law, statutory, and public policy requirements: including, but not limited to, those protecting free speech, religious liberty, public welfare, the environment, and prohibiting discrimination.

VIII. Other Information

None.

Authority: Pub. L. 110–289. 12 U.S.C. 4701, 12 CFR part 1805, 12 CFR part 1807, 12 CFR part 1815, 12 U.S.C. 4502.

Jodie L. Harris,

Director, Community Development Financial Institutions Fund.

[FR Doc. 2020–11580 Filed 5–28–20; 8:45 am]

BILLING CODE 4810–70–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

[Docket ID OCC–2020–0021]

Minority Depository Institutions Advisory Committee; Meeting

AGENCY: Office of the Comptroller of the Currency, Department of the Treasury.

ACTION: Notice of meeting.

SUMMARY: The Office of the Comptroller of the Currency (OCC) announces a meeting of the Minority Depository Institutions Advisory Committee (MDIAC).

DATES: The OCC MDIAC will hold a public meeting on Wednesday, June 17, 2020, via remote means beginning at 10:00 a.m. Eastern Daylight Time (EDT).

ADDRESSES: The OCC will hold the June 17, 2020 meeting of the MDIAC via remote means.

FOR FURTHER INFORMATION CONTACT: Beverly Cole, Designated Federal Officer and Deputy Comptroller for the Northeastern District, (212) 790–4001, Office of the Comptroller of the Currency, 340 Madison Ave., Fifth Floor, New York, New York 10173.

SUPPLEMENTARY INFORMATION: By this notice, the OCC is announcing that the MDIAC will convene a meeting at 10:00 a.m. EDT on Wednesday, June 17, 2020, via remote means. Agenda items will include current topics of interest to the industry. The purpose of the meeting is for the MDIAC to advise the OCC on steps the agency may be able to take to ensure the continued health and viability of minority depository institutions and other issues of concern to minority depository institutions. Members of the public may submit written statements to the MDIAC by email to: *MDIAC@OCC.treas.gov*.

The OCC must receive written statements no later than 5:00 p.m. EDT on Wednesday, June 10, 2020. Members of the public who plan to attend the meeting via remote means should contact the OCC by 5:00 p.m. EDT on Wednesday, June 10, 2020, to inform the OCC of their desire to attend the meeting and to obtain information about participation via remote means. Members of the public may contact the OCC via email at *MDIAC@OCC.treas.gov* or by telephone at (212) 790–4001. Attendees should provide their full name, email address, and organization, if any. Members of the public who are hearing impaired should call (202) 649–5597 (TTY) no later than 5:00 p.m. EDT on Wednesday, June 10, 2020, to arrange auxiliary aids such as sign language interpretation for this meeting.

Brian P. Brooks,

First Deputy Comptroller of the Currency.

[FR Doc. 2020–11575 Filed 5–28–20; 8:45 am]

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FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 412, 413, et al.
Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 412, 413, 417, 476, 480, 484, and 495

[CMS–1735–P]

RIN 0938–AU11

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2021 Rates; Quality Reporting and Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: We are proposing to revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from our continuing experience with these systems for FY 2021 and to implement certain recent legislation. We also are proposing to make changes relating to Medicare graduate medical education (GME) for teaching hospitals. In addition, we are providing the market basket update that will apply to the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis, subject to these limits for FY 2021. We are proposing to update the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) for FY 2021. In this FY 2021 IPPS/LTCH PPS proposed rule, we are proposing changes to the new technology add-on payment pathway for certain antimicrobial products and other changes to new technology add-on payment policies, and to collect market-based rate information on the Medicare cost report for cost reporting periods ending on or after January 1, 2021, and requesting comment on a potential market based MS–DRG relative weight methodology beginning in FY 2024 that we may adopt in this rulemaking. We are proposing to establish new requirements or revise existing requirements for quality reporting by acute care hospitals and PPS-exempt cancer hospitals. We also are proposing to establish new requirements and revise existing requirements for eligible hospitals and critical access hospitals (CAHs) participating in the Medicare and Medicaid Promoting Interoperability Programs. We are providing estimated and newly established performance standards for the Hospital Value-Based Purchasing (VBP) Program, and proposing updated policies for the Hospital Readmissions Reduction Program and the Hospital-Acquired Condition (HAC) Reduction Program.

DATES: To be assured consideration, comments must be received at one of the addresses provided in the **ADDRESSES** section, no later than 5 p.m. EDT on July 10, 2020.

ADDRESSES: In commenting, please refer to file code CMS–1735–P. 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–1735–P, P.O. Box 8013, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1735–P, Mail Stop C4–26–05, 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: Donald Thompson, (410) 786–4487, and Michele Hudson, (410) 786–4487, Operating Prospective Payment, MS–DRGs, Wage Index, New Medical Service and Technology Add-On Payments, Hospital Geographic Reclassifications, Graduate Medical Education, Capital Prospective Payment, Excluded Hospitals, Medicare Disproportionate Share Hospital (DSH) Payment Adjustment, Medicare-Dependent Small Rural Hospital (MDH) Program, Low-Volume Hospital Payment Adjustment, and Critical Access Hospital (CAH) Issues.

Michele Hudson, (410) 786–4487 and Emily Lipkin, (410) 786–3633, Long-Term Care Hospital Prospective Payment System and MS–LTC–DRG Relative Weights Issues.

Emily Forrest, (202) 205–1922, Market Based Data Collection and Potential Market Based MS–DRG Relative Weight Methodology Issues.

Siddhartha Mazumdar, (410) 786–6673, Rural Community Hospital Demonstration Program Issues.

Jeris Smith, (410) 786–0110, Frontier Community Health Integration Project Demonstration Issues.

Erin Patton, (410) 786–2437, Hospital Readmissions Reduction Program—Administration Issues.

James Poyer, (410) 786–2261, Hospital Readmissions Reduction Program—Readmissions—Measures Issues.

Michael Brea, (410) 786–4961, Hospital-Acquired Condition Reduction Program—Administration Issues.

Annese Abdullah-Mclaughlin, (410) 786–2995, Hospital-Acquired Condition Reduction Program—Measures Issues.

Julia Venanzi, (410) 786–1471 and Katrina Hoadley, (410) 786–8490, Hospital Inpatient Quality Reporting Program.

Julia Venanzi, (410) 786–1471 and Pamela Brown (410) 786–3940, Hospital Value-Based Purchasing Program.

Katrina Hoadley, (410) 786–8490, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing—Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues.

Elizabeth Goldstein, (410) 786–6665, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing—Hospital Consumer Assessment of Healthcare Providers and Systems Measures Issues.

Erin Patton, (410) 786–2437 and Ronique Evans, (410) 786–1000, PPS-Exempt Cancer Hospital Quality Reporting Issues.

Mary Pratt, (410) 786–6867, Long-Term Care Hospital Quality Data Reporting Issues.

Dylan Podson (410) 786–5031, Jessica Warren (410) 786–7519, and Elizabeth Holland, (410) 786–1309, Promoting Interoperability Programs.

Steve Rubio, (410) 786–1782, Reimbursement for Submission of Patient Records to Beneficiary and Family Centered Care Quality Improvement Organizations (BFCC–QIOs) in Electronic Format.

Maude Shepard, (410) 786–5598, Provider Reimbursement Review Board Electronic Filing.

Kellie Shannon, (410) 786–0416 and Bob Kuhl, (443) 896–8410, Medicare Bad Debt.

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.

Tables Available Through the Internet on the CMS Website

The IPPS tables for this FY 2021 proposed rule are available through the internet on the CMS website at: *https://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 2021 IPPS Proposed Rule Home Page'' or ''Acute Inpatient—Files for Download.'' The LTCH PPS tables for this FY 2021 proposed rule are available through the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1735–P. For further details on the contents of the tables referenced in this proposed rule, we refer readers to section VI. of the Addendum to this FY 2021 IPPS/LTCH PPS proposed rule.

Readers who experience any problems accessing any of the tables that are posted on the CMS websites, as previously identified, should contact Michael Treitel at (410) 786–4552.

I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

This FY 2021 IPPS/LTCH PPS proposed rule would make payment and policy changes under the Medicare inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals as well as for certain hospitals and hospital units excluded from the IPPS. In addition, it would make payment and policy changes for inpatient hospital services provided by long-term care hospitals (LTCHs) under the long-term care hospital prospective payment system (LTCH PPS). This proposed rule also would make policy changes to programs associated with Medicare IPPS hospitals, IPPS-excluded hospitals, and LTCHs. In this FY 2021 proposed rule, we are continuing policies to address wage index disparities impacting low wage index hospitals; and including proposals related to new technology add-on payments for certain antimicrobial products, other proposals related to new technology add-on payments, and to collect market-based rate information on the Medicare cost report for cost reporting periods ending on or after January 1, 2021, and requesting comment on a potential market based MS–DRG relative weight methodology beginning in FY 2024 that we may adopt in this rulemaking.

We are proposing to establish new requirements and revise existing requirements for quality reporting by acute care hospitals and PPS-exempt cancer hospitals that participate in Medicare. We also are proposing to establish new requirements and revise existing requirements for eligible hospitals and CAHs participating in the Medicare and Medicaid Promoting Interoperability Programs.

We are providing estimated and newly established performance standards for the Hospital Value-Based Purchasing (VBP) Program, and proposing updated policies for the Hospital Readmissions Reduction Program and the Hospital-Acquired Condition (HAC) Reduction Program.

Under various statutory authorities, we either discuss continued program implementation or are proposing to make changes to the Medicare IPPS, to the LTCH PPS, and to other related payment methodologies and programs for FY 2021 and subsequent fiscal years. These statutory authorities include, but are not limited to, the following:

- Section 1886(d) of the Social Security Act (the Act), which sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires that, instead of paying for capital-related costs of inpatient hospital services on a reasonable cost basis, the Secretary use a prospective payment system (PPS).
- Section 1886(d)(1)(B) of the Act, which specifies that certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Rehabilitation hospitals and units; LTCHs; psychiatric hospitals and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS.
- Sections 123(a) and (c) of the BBRA Public Law (Pub. L. 106–113) and section 307(b)(1) of the BIPA (Pub. L. 106–554) (as codified under section 1886(m)(1) of the Act), which provide for the development and implementation of a prospective payment system for payment for inpatient hospital services of LTCHs described in section 1886(d)(1)(B)(iv) of the Act.
- Sections 1814(l), 1820, and 1834(g) of the Act, which specify that payments are made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services and that these payments are generally based on 101 percent of reasonable cost.
- Section 1866(k) of the Act, which provides for the establishment of a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act, referred to as ''PPS-exempt cancer hospitals.''
- Section 1886(a)(4) of the Act, which specifies that costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act.
- Section 1886(b)(3)(B)(viii) of the Act, which requires the Secretary to reduce the applicable percentage increase that would otherwise apply to the standardized amount applicable to a subsection (d) hospital for discharges occurring in a fiscal year if the hospital does not submit data on measures in a form and manner, and at a time, specified by the Secretary.
- Section 1886(o) of the Act, which requires the Secretary to establish a Hospital Value-Based Purchasing (VBP) Program, under which value-based incentive payments are made in a fiscal year to hospitals meeting performance standards established for a performance period for such fiscal year.
- Section 1886(p) of the Act, which establishes a Hospital-Acquired Condition (HAC) Reduction Program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce hospital-acquired conditions.
- Section 1886(q) of the Act, as amended by section 15002 of the 21st

Century Cures Act, which establishes the Hospital Readmissions Reduction Program. Under the program, payments for discharges from an applicable hospital as defined under section 1886(d) of the Act will be reduced to account for certain excess readmissions. Section 15002 of the 21st Century Cures Act directs the Secretary to compare hospitals with respect to the number of their Medicare-Medicaid dual-eligible beneficiaries (dual-eligibles) in determining the extent of excess readmissions.

- Section 1886(r) of the Act, as added by section 3133 of the Affordable Care Act, which provides for a reduction to disproportionate share hospital (DSH) payments under section 1886(d)(5)(F) of the Act and for a new uncompensated care payment to eligible hospitals. Specifically, section 1886(r) of the Act requires that, for fiscal year 2014 and each subsequent fiscal year, subsection (d) hospitals that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act will receive two separate payments: (1) 25 percent of the amount they previously would have received under section 1886(d)(5)(F) of the Act for DSH (''the empirically justified amount''), and (2) an additional payment for the DSH hospital's proportion of uncompensated care, determined as the product of three factors. These three factors are: (1) 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act; (2) 1 minus the percent change in the percent of individuals who are uninsured; and (3) a hospital's uncompensated care amount relative to the uncompensated care amount of all DSH hospitals expressed as a percentage.
- Section 1886(m)(6) of the Act, as added by section 1206(a)(1) of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67) and amended by section 51005(a) of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), which provided for the establishment of site neutral payment rate criteria under the LTCH PPS, with implementation beginning in FY 2016. Section 51005(b) of the Bipartisan Budget Act of 2018 amended section 1886(m)(6)(B) by adding new clause (iv), which specifies that the IPPS comparable amount defined in clause (ii)(I) shall be reduced by 4.6 percent for FYs 2018 through 2026.
- Section 1899B of the Act, as added by section 2(a) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185), which provides for the establishment of standardized data reporting for certain post-acute care providers, including LTCHs.

2. Waiver of the 60-Day Delayed Effective Date for the Final Rule

The United States is responding to an outbreak of respiratory disease caused by a novel (new) coronavirus that has now been detected in more than 190 locations internationally, including in all 50 States and the District of Columbia. The virus has been named ''SARS–CoV–2'' and the disease it causes has been named ''coronavirus disease 2019'' (abbreviated ''COVID–19'').

Due to the significant devotion of resources to the COVID–19 response, as discussed and for the reasons discussed in section XI.D. of the preamble of this propose rule, we are hereby waiving the 60-day delay in the effective date of the final rule, and replacing it with a 30-day delay in the effective date of the final rule.

3. Summary of the Major Provisions

The following is a summary of the major provisions in this proposed rule. In general, these major provisions are being proposed as part of the annual update to the payment policies and payment rates, consistent with the applicable statutory provisions. A general summary of the proposed changes in this proposed rule is presented in section I.D. of the preamble of this proposed rule.

a. Proposed MS–DRG Documentation and Coding Adjustment

Section 631 of the American Taxpayer Relief Act of 2012 (ATRA, Pub. L. 112–240) amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment to the standardized amount of Medicare payments to acute care hospitals to account for changes in MS–DRG documentation and coding that do not reflect real changes in case-mix, totaling $11 billion over a 4-year period of FYs 2014, 2015, 2016, and 2017. The FY 2014 through FY 2017 adjustments represented the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013. Prior to the ATRA, this amount could not have been recovered under Public Law 110–90. Section 414 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percent positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. (The FY 2018 adjustment was subsequently adjusted to 0.4588 percent by section 15005 of the 21st Century Cures Act.) Therefore, for FY 2021, we are proposing to make an adjustment of + 0.5 percent to the standardized amount.

b. Proposed Changes to the New Technology Add-On Payment Policy for Certain Antimicrobial Products

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297), we established an alternative inpatient new technology add-on payment pathway for certain antimicrobial products in light of the significant concerns related to the ongoing public health crisis represented by antimicrobial resistance. Under this alternative pathway, if a medical product receives the FDA's Qualified Infectious Disease Product (QIDP) designation and received FDA marketing authorization, such a product will be considered new and not substantially similar to an existing technology for purposes of new technology add-on payment under the IPPS and will not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

In light of recent information that continues to highlight the significant concerns and impacts related to antimicrobial resistance and emphasizes the continued importance of this issue both with respect to Medicare beneficiaries and public health overall, we are proposing changes to the new technology add-on payment policy for certain antimicrobials for FY 2021.

As discussed in section II.G.9.b. of the preamble of this proposed rule, we are proposing to expand our alternative new technology add-on payment pathway for QIDPs to include products approved through FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD pathway). Under this proposal, for applications received for new technology add-on payments for FY 2022 and subsequent fiscal years, if an antimicrobial product is approved through FDA's LPAD pathway, it will be considered new and not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and will not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

Under current policy, a new technology must receive FDA marketing

authorization (for example, approval or clearance) by July 1 to be considered in the final rule in order to allow complete review and consideration of all the information to determine if the technology meets the new technology add-on payment criteria. For the reasons discussed in section II.G.9.c. of the preamble of this proposed rule, we are proposing to provide for conditional new technology add-on payment approval for products designated as QIDPs that do not receive FDA marketing authorization by July 1 and products that do not receive approval through FDA's LPAD pathway by July 1 but otherwise meet the applicable add-on payment criteria. Under this proposal, cases involving eligible antimicrobial products would begin receiving the new technology add-on payment sooner, effective for discharges the quarter after the date of FDA marketing authorization provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments.

c. Continuation of the Low Wage Index Hospital Policy

To help mitigate wage index disparities between high wage and low hospitals, in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42326 through 42332), we adopted a policy to provide an opportunity for certain low wage index hospitals to increase employee compensation by increasing the wage index values for certain hospitals with low wage index values (the low wage index hospital policy). This policy was adopted in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals. We also indicated that this policy would be effective for at least 4 years, beginning in FY 2020, in order to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation. Therefore, for FY 2021, we are continuing the low wage index hospital policy, and also applying this policy in a budget neutral manner by proposing an adjustment to the standardized amounts.

d. Proposed DSH Payment Adjustment and Additional Payment for Uncompensated Care

Section 3133 of the Affordable Care Act modified the Medicare disproportionate share hospital (DSH) payment methodology beginning in FY 2014. Under section 1886(r) of the Act, which was added by section 3133 of the Affordable Care Act, starting in FY 2014, DSHs receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments in section 1886(d)(5)(F) of the Act. The remaining amount, equal to 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, is paid as additional payments after the amount is reduced for changes in the percentage of individuals that are uninsured. Each Medicare DSH will receive an additional payment based on its share of the total amount of uncompensated care for all Medicare DSHs for a given time period.

In this proposed rule, we set forth our proposed estimates of the three factors used to determine uncompensated care payments for FY 2021. We are proposing to continue to use uninsured estimates produced by CMS' Office of the Actuary (OACT) as part of the development of the National Health Expenditure Accounts (NHEA) in the calculation of Factor 2. In addition, we are proposing to use a single year of data on uncompensated care costs from Worksheet S–10 of the FY 2017 cost reports to calculate Factor 3 in the FY 2021 methodology for all eligible hospitals with the exception of Indian Health Service (IHS) and Tribal hospitals and Puerto Rico hospitals. For IHS and Tribal hospitals and Puerto Rico hospitals we are proposing to continue to use the low-income insured days proxy to calculate Factor 3 for these hospitals for 1 more year. Furthermore, we are proposing to calculate Factor 3 for all subsequent fiscal years for all eligible hospitals, except IHS and Tribal hospitals, using the most recent available single year of audited Worksheet S–10 data. We are also making other methodological proposals for calculating Factor 3 for FY 2021.

e. Reduction of Hospital Payments for Excess Readmissions

We are proposing to make changes to policies for the Hospital Readmissions Reduction Program, which was established under section 1886(q) of the Act, as amended by section 15002 of the 21st Century Cures Act. The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions. For FY 2017 and subsequent years, the reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG) surgery. In this FY 2021 IPPS/LTCH PPS proposed rule, we are proposing the following policies: (1) To automatically adopt applicable periods beginning with the FY 2023 program year and all subsequent program years, unless otherwise specified by the Secretary; and (2) to update the definition of *applicable period* at 42 CFR 412.152 to align with this proposal.

f. Hospital Value-Based Purchasing (VBP) Program

Section 1886(o) of the Act requires the Secretary to establish a Hospital VBP Program under which value-based incentive payments are made in a fiscal year to hospitals based on their performance on measures established for a performance period for such fiscal year. In this FY 2021 IPPS/LTCH PPS proposed rule, we are providing estimated and newly established performance standards for certain measures for the FY 2023 program year, the FY 2024 program year, the FY 2025 program year, and the FY 2026 program year.

g. Hospital-Acquired Condition (HAC) Reduction Program

Section 1886(p) of the Act establishes an incentive to hospitals to reduce the incidence of hospital-acquired conditions by requiring the Secretary to make an adjustment to payments to applicable hospitals, effective for discharges beginning on October 1, 2014. This 1-percent payment reduction applies to hospitals that rank in the worst-performing quartile (25 percent) of all applicable hospitals, relative to the national average, of conditions acquired during the applicable period and on all of the hospital's discharges for the specified fiscal year. In this FY 2021 IPPS/LTCH PPS proposed rule, we are proposing the following policies: (1) To automatically adopt applicable periods beginning with the FY 2023 program year and all subsequent program years, unless otherwise specified by the secretary, (2) to make refinements to the process for validation of HAC Reduction Program measure data in alignment with the Hospital IQR Program validation proposals; and (3) to update the definition of *applicable period* at 42 CFR 412.170 to align with the proposal to automatically adopt applicable periods.

h. Hospital Inpatient Quality Reporting (IQR) Program

Under section 1886(b)(3)(B)(viii) of the Act, subsection (d) hospitals are required to report data on measures

selected by the Secretary for a fiscal year in order to receive the full annual percentage increase that would otherwise apply to the standardized amount applicable to discharges occurring in that fiscal year.

In this FY 2021 IPPS/LTCH PPS proposed rule, we are proposing reporting, submission, and public display requirements for eCQMs, including policies to: (1) Progressively increase the numbers of quarters of eCQM data reported, from one self-selected quarter of data to four quarters of data over a 3-year period, by requiring hospitals to report: (a) Two quarters of data for the CY 2021 reporting period/FY 2023 payment determination; (b) three quarters of data for the CY 2022 reporting period/FY 2024 payment determination; and (c) four quarters of data beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years, while continuing to allow hospitals to report: (i) Three self-selected eCQMs, and (ii) the Safe Use of Opioids eCQM; and (2) begin public display of eCQM data beginning with data reported by hospitals for the CY 2021 reporting period and for subsequent years. The eCQM-related proposals are in alignment with proposals under the Promoting Interoperability Program. We also are proposing to expand the requirement to use EHR technology certified to the 2015 Edition for submitting data on not only the previously finalized Hybrid Hospital-Wide Readmission measure, but all hybrid measures in the Hospital IQR Program.

We also are proposing to make several changes to streamline validation processes under the Hospital IQR Program. We are proposing to: (1) Require the use of electronic file submissions via a CMS-approved secure file transmission process and no longer allow the submission of paper copies of medical records or copies on digital portable media such as CD, DVD, or flash drive; (2) combine the validation processes for chart-abstracted measures and eCQMs by: (a) Aligning data submission quarters; (b) combining hospital selection, including: (i) Reducing the pool of hospitals randomly selected for chart-abstracted measure validation; and (ii) integrating and applying targeting criteria for eCQM validation; (c) removing previous exclusion criteria; and (d) combining scoring processes by providing one combined validation score for the validation of chart-abstracted measures and eCQMs with the eCQM portion of the combined score weighted at zero; and (3) formalize the process for conducting educational reviews for eCQM validation in alignment with current processes for providing feedback for chart-abstracted validation results.

h. PPS-Exempt Cancer Hospital Quality Reporting Program

Section 1866(k)(1) of the Act requires, for purposes of FY 2014 and each subsequent fiscal year, that a hospital described in section 1886(d)(1)(B)(v) of the Act (a PPS-exempt cancer hospital, or a PCH) submit data in accordance with section 1866(k)(2) of the Act with respect to such fiscal year. There is no financial impact to PCH Medicare payment if a PCH does not participate.

In this FY 2021 IPPS/LTCH PPS proposed rule, we are proposing to refine two existing program measures, Catheter-associated Urinary Tract infection (CAUTI) (NQF #0138) and Central Line-associated Bloodstream Infection (CLABSI) (NQF #0139), to adopt the updated SIR calculation methodology developed by the Center for Disease Control and Prevention (CDC) that calculates rates using updated HAI baseline data that are further stratified by patient location. We are also proposing to publicly display the refined versions of the measures beginning in the fall of CY 2022.

i. Medicare and Medicaid Promoting Interoperability Programs

For purposes of an increased level of stability, reducing the burden on eligible hospitals and CAHs, and clarifying certain existing policies, we are proposing several changes to the Medicare Promoting Interoperability Program. Specifically, we are proposing: (1) An EHR reporting period of a minimum of any continuous 90-day period in CY 2022 for new and returning participants (eligible hospitals and CAHs); (2) to maintain the Electronic Prescribing Objective's Query of PDMP measure as optional and worth 5 bonus points in CY 2021; (3) to modify the name of the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure; (4) to progressively increase the number of quarters for which hospitals are required to report eCQM data, from the current requirement of one self-selected calendar quarter of data, to four calendar quarters of data, over a 3-year period. Specifically, we propose to require: (a) 2 self-selected calendar quarters of data for the CY 2021 reporting period; (b) 3 self-selected calendar quarters of data for the CY 2022 reporting period; and (c) 4 self-selected calendar quarters of data beginning with the CY 2023 reporting period, where the proposed submission period for the Medicare Promoting Interoperability Program would be the 2 months following the close of the CY 2023 (ending February 28, 2024); (5) to begin publicly reporting eCQM performance data beginning with the eCQM data reported by eligible hospitals and CAHs for the reporting period in CY 2021 on the *Hospital Compare* and/or *data.medicare.gov* websites or successor websites; (6) to correct errors and amend regulation text under 495.104(c)(5)(viii)(B) through (D) regarding transition factors under section 1886(n)(2)(E)(i) for the incentive payments for Puerto Rico eligible hospitals; and (7) to correct errors and amend regulation text under § 495.20(e)(5)(iii) and (l)(11)(ii)(C)(*1*) for regulatory citations for the ONC certification criteria. We are amending our regulation texts as necessary to incorporate these proposed changes.

j. Market-Based MS–DRG Relative Weight Proposed Data Collection and Potential Change in Methodology for Calculating MS–DRG Relative Weights

As discussed in section IV.P. of the preamble of this proposed rule, in order to reduce the Medicare program's reliance on the hospital chargemaster, thereby advancing the critical goals of Executive Orders 13813, *Promoting Healthcare Choice and Competition Across the United States* and 13890, *Protecting and Improving Medicare for Our Nation's Seniors,* and to support the development of a market-based approach to payment under the Medicare FFS system, we are proposing that hospitals would be required to report certain market-based payment rate information on their Medicare cost report for cost reporting periods ending on or after January 1, 2021, to be used in a potential change to the methodology for calculating the IPPS MS–DRG relative weights to reflect relative market-based pricing

We are specifically proposing that hospitals would report on the Medicare cost report: (1) The median payer-specific negotiated charge that the hospital has negotiated with all of its Medicare Advantage (MA) organizations (also referred to as MA organizations) payers, by MS–DRG; and (2) the median payer-specific negotiated charge the hospital has negotiated with all of its third-party payers, which would include MA organizations, by MS–DRG. The market-based rate information we are proposing to collect on the Medicare cost report would be the median of the payer-specific negotiated charges by MS–DRG, as described previously, for a hospital's MA organization payers and all of its third party payers. The payer-

specific negotiated charges used by hospitals to calculate these medians would be the payer-specific negotiated charges for service packages that hospitals are required to make public under the requirements we finalized in the Hospital Price Transparency Final Rule (84 FR 65524) that can be cross-walked to an MS–DRG. We believe that because hospitals are already required to publically report payer-specific negotiated charges, in accordance with the Hospital Price Transparency Final Rule, that the additional calculation and reporting of the median payer-specific negotiated charge will be less burdensome for hospitals.

We are also seeking comment on a potential change to the methodology for calculating the IPPS MS–DRG relative weights to incorporate this market-based rate information, beginning in FY 2024, which we may consider adopting in the FY 2021 IPPS/LTCH PPS final rule. This potential MS–DRG relative weight methodology would utilize the proposed median payer-specific negotiated charge information, collected on the cost report, for calculating the MS–DRG relative weights.

4. Summary of Costs and Benefits

• *Proposed Adjustment for MS–DRG Documentation and Coding Changes.* Section 414 of the MACRA replaced the single positive adjustment we intended to make in FY 2018 once the recoupment required by section 631 of the ATRA was complete with a 0.5 percentage point positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. (The FY 2018 adjustment was subsequently adjusted to 0.4588 percentage point by section 15005 of the 21st Century Cures Act.) For FY 2021, we are proposing to make an adjustment of +0.5 percentage point to the standardized amount consistent with the MACRA.

• *Proposed Changes to the New Technology Add-On Payment Policy for Certain Antimicrobial Products.* In light of recent information that continues to highlight the significant concerns and impacts related to antimicrobial resistance and emphasizes the continued importance of this issue both with respect to Medicare beneficiaries and public health overall, we are proposing changes to the new technology add-on payment policy for certain antimicrobials for FY 2021. We are proposing to expand our alternative new technology add-on payment pathway for QIDPs to include products approved through FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD pathway). Under this proposal, for applications received for new technology add-on payments for FY 2022 and subsequent fiscal years, if an antimicrobial product is approved through FDA's LPAD pathway, it will be considered new and not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and will not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

We are also proposing to provide for conditional new technology add-on payment approval for products designated as QIDPs that do not receive FDA marketing authorization by July 1 and products that do not receive approval through FDA's LPAD pathway by July 1 (the current deadline for consideration in the final rule) but otherwise meet the applicable add-on payment criteria. Under this proposal, cases involving eligible antimicrobial products would begin receiving the new technology add-on payment sooner, effective for discharges the quarter after the date of FDA marketing authorization provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments. Given the relatively recent introduction of the FDA's LPAD pathway there have not been any drugs that were approved under the FDA's LPAD pathway that applied for a new technology add-on payment under the IPPS. If all of the future LPADs that would have applied for new technology add-on payments would have been approved under existing criteria, this proposal has no impact relative to current policy. To the extent that there are future LPADs that are the subject of applications for new technology add-on payments, and those applications would have been denied under the current new technology add-on payment criteria, this proposal is a cost, but that cost is not estimable. Therefore, it is not possible to quantify the impact of these proposed policies.

• *Wage Index Disparities Between High and Low Wage Index Hospitals.* As discussed in section III.G.3. of the preamble of this proposed rule, we are continuing to reduce the disparity between high and low wage index hospitals by increasing the wage index values for certain hospitals with low wage index values and proposing to apply a budget neutrality adjustment to the standardized amount so that increase is implemented in a budget neutral manner.

• *Proposed Medicare DSH Payment Adjustment and Additional Payment for Uncompensated Care.* For FY 2021, we are proposing to update our estimates of the three factors used to determine uncompensated care payments. We are proposing to continue to use uninsured estimates produced by OACT as part of the development of the NHEA in the calculation of Factor 2. We also are proposing to use a single year of data on uncompensated care costs from Worksheet S–10 for FY 2017 to determine Factor 3 for FY 2021. To determine the amount of uncompensated care for purposes of calculating Factor 3 for Puerto Rico hospitals and Indian Health Service and Tribal hospitals, we are proposing to continue to use only data regarding low-income insured days for FY 2013. We project that the amount available to distribute as payments for uncompensated care for FY 2021 would decrease by approximately $534 million, as compared to our estimate of the uncompensated care payments that will be distributed in FY 2020. The payments have redistributive effects, based on a hospital's uncompensated care amount relative to the uncompensated care amount for all hospitals that are projected to be eligible to receive Medicare DSH payments, and the calculated payment amount is not directly tied to a hospital's number of discharges.

• *Proposed Update to the LTCH PPS Payment Rates and Other Payment Policies.* Based on the best available data for the 360 LTCHs in our database, we estimate that the proposed changes to the payment rates and factors that we present in the preamble of and Addendum to this proposed rule, which reflect the end of the transition of the statutory application of the site neutral payment rate and the proposed update to the LTCH PPS standard Federal payment rate for FY 2021, would result in an estimated decrease in payments in FY 2021 of approximately $36 million.

• *Changes to the Hospital Readmissions Reduction Program.* For FY 2021 and subsequent years, the reduction is based on a hospital's risk-adjusted readmission rate during a 3-year period for acute myocardial infarction (AMI), heart failure (HF), pneumonia, chronic obstructive pulmonary disease (COPD), elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA), and coronary artery bypass graft (CABG) surgery. For the proposed rule, we are not providing updated estimates based on the proxy file due to timing. Instead, we reiterate the information contained in the FY 2020 IPPS/LTCH PPS final rule, in

which we estimated that 2,583 hospitals would have their base operating DRG payments reduced by their FY 2020 hospital-specific payment adjustment factors. As a result, we estimated that the Hospital Readmissions Reduction Program will save approximately $563 million in FY 2020. We will update these estimates in the FY 2021 IPPS/LTCH PPS final rule as the data become available.

• *Value-Based Incentive Payments under the Hospital VBP Program.* We estimate that there will be no net financial impact to participating hospitals under the Hospital VBP Program for the FY 2021 program year in the aggregate because, by law, the amount available for value-based incentive payments under the program in a given year must be equal to the total amount of base operating MS–DRG payment amount reductions for that year, as estimated by the Secretary. The estimated amount of base operating MS–DRG payment amount reductions for the FY 2021 program year and, therefore, the estimated amount available for value-based incentive payments for FY 2021 discharges is approximately $1.9 billion.

• *Changes to the HAC Reduction Program.* A hospital's Total HAC Score and its ranking in comparison to other hospitals in any given year depend on several different factors. We are making no changes to the scoring methodology, which will continue to use the Winsorized z-score and equal measure weights approaches to determine the worst-performing quartile of hospitals. Any significant impact due to the HAC Reduction Program changes for FY 2021, including which hospitals will receive the adjustment, will depend on the actual experience of hospitals in the Program.

• *Changes to the Hospital Inpatient Quality Reporting (IQR) Program.* Across 3,300 IPPS hospitals, we estimate that our proposed changes for the Hospital IQR Program in this proposed rule would result in a total information collection burden increase of 6,533 hours associated with our proposed policies and updated burden estimates and a total cost increase of approximately $253,480, across a 4-year period from the CY 2021 reporting period/FY 2023 payment determination through the CY 2024 reporting period/FY 2026 payment determination.

• *Changes to the Medicare and Medicaid Promoting Interoperability Programs.* If our proposals are finalized, we estimate a minor net reduction in burden hours due to correcting a previously mistaken burden calculation in last year's final rule, as well as a slight increase in total cost for the Medicare Promoting Interoperability Program for CY 2021. Unrelated to any of this rule's Promoting Interoperability Program proposals, the increased alteration to the annual information collection's total cost is due to utilizing an updated hourly wage rate for the necessary hospital staff involved in attesting to the objectives and measures under 42 CFR 495.24(e). The Bureau of Labor Statistics (BLS) recently released a 2018 wage rate which, compared to the 2017 rates used in FY 2020 IPPS/LTCH PPS final rule, would result in an estimated increase of $21,022.32 for the annual information collection burden (total cost) in FY 2021. Therefore, multiplying the total annual burden of 21,450 hours by the 2018 BLS labor cost of $69.34, we estimate the Promoting Interoperability Program's total cost to be $1,487,343 for the CY 2021 EHR reporting period (21,450 hours × $69.34).

• *Market-Based MS–DRG Relative Weight Proposed Data Collection and Potential Change in Methodology for Calculating MS–DRG Relative Weights.* In section IV.P.4. of the preamble of this proposed rule, we are seeking comment on a potential methodology for estimating the MS–DRG relative weights beginning in FY 2024 based on the median payer-specific negotiated charge information we are proposing to collect on the cost report and which we may consider adopting in the FY 2021 IPPS/LTCH PPS final rule. We note that the estimated total annual burden hours for this proposal are as follows: 3,189 hospitals times 15 hours per hospital equals 47,835 annual burden hours and $3,096,838. We refer readers to section XI.B.11. of the preamble of this proposed rule for further analysis of this assessment.

B. Background Summary

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

Section 1886(d) of the the Act sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires the Secretary to use a prospective payment system (PPS) to pay for the capital-related costs of inpatient hospital services for these ''subsection (d) hospitals.'' Under these PPSs, Medicare payment for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. Discharges are classified according to a list of diagnosis-related groups (DRGs).

The base payment rate is comprised of a standardized amount that is divided into a labor-related share and a nonlabor-related share. The labor-related share is adjusted by the wage index applicable to the area where the hospital is located. If the hospital is located in Alaska or Hawaii, the nonlabor-related share is adjusted by a cost-of-living adjustment factor. This base payment rate is multiplied by the DRG relative weight.

If the hospital treats a high percentage of certain low-income patients, it receives a percentage add-on payment applied to the DRG-adjusted base payment rate. This add-on payment, known as the disproportionate share hospital (DSH) adjustment, provides for a percentage increase in Medicare payments to hospitals that qualify under either of two statutory formulas designed to identify hospitals that serve a disproportionate share of low-income patients. For qualifying hospitals, the amount of this adjustment varies based on the outcome of the statutory calculations. The Affordable Care Act revised the Medicare DSH payment methodology and provides for a new additional Medicare payment beginning on October 1, 2013, that considers the amount of uncompensated care furnished by the hospital relative to all other qualifying hospitals.

If the hospital is training residents in an approved residency program(s), it receives a percentage add-on payment for each case paid under the IPPS, known as the indirect medical education (IME) adjustment. This percentage varies, depending on the ratio of residents to beds.

Additional payments may be made for cases that involve new technologies or medical services that have been approved for special add-on payments. In general, to qualify, a new technology or medical service must demonstrate that it is a substantial clinical improvement over technologies or services otherwise available, and that, absent an add-on payment, it would be inadequately paid under the regular DRG payment. In addition, certain transformative new devices and certain antimicrobial products may qualify under an alternative inpatient new technology add-on payment pathway by demonstrating that, absent an add-on payment, they would be inadequately paid under the regular DRG payment.

The costs incurred by the hospital for a case are evaluated to determine whether the hospital is eligible for an additional payment as an outlier case. This additional payment is designed to protect the hospital from large financial losses due to unusually expensive cases.

Any eligible outlier payment is added to the DRG-adjusted base payment rate, plus any DSH, IME, and new technology or medical service add-on adjustments.

Although payments to most hospitals under the IPPS are made on the basis of the standardized amounts, some categories of hospitals are paid in whole or in part based on their hospital-specific rate, which is determined from their costs in a base year. For example, sole community hospitals (SCHs) receive the higher of a hospital-specific rate based on their costs in a base year (the highest of FY 1982, FY 1987, FY 1996, or FY 2006) or the IPPS Federal rate based on the standardized amount. SCHs are the sole source of care in their areas. Specifically, section 1886(d)(5)(D)(iii) of the Act defines an SCH as a hospital that is located more than 35 road miles from another hospital or that, by reason of factors such as an isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of hospital inpatient services reasonably available to Medicare beneficiaries. In addition, certain rural hospitals previously designated by the Secretary as essential access community hospitals are considered SCHs.

Under current law, the Medicare-dependent, small rural hospital (MDH) program is effective through FY 2022. For discharges occurring on or after October 1, 2007, but before October 1, 2022, an MDH receives the higher of the Federal rate or the Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the highest of its FY 1982, FY 1987, or FY 2002 hospital-specific rate. MDHs are a major source of care for Medicare beneficiaries in their areas. Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area (or, as amended by the Bipartisan Budget Act of 2018, a hospital located in a State with no rural area that meets certain statutory criteria), has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (not less than 60 percent of its inpatient days or discharges in its cost reporting year beginning in FY 1987 or in two of its three most recently settled Medicare cost reporting years).

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient hospital services in accordance with a prospective payment system established by the Secretary. The basic methodology for determining capital prospective payments is set forth in our regulations at 42 CFR 412.308 and 412.312. Under the capital IPPS, payments are adjusted by the same DRG for the case as they are under the operating IPPS. Capital IPPS payments are also adjusted for IME and DSH, similar to the adjustments made under the operating IPPS. In addition, hospitals may receive outlier payments for those cases that have unusually high costs.

The existing regulations governing payments to hospitals under the IPPS are located in 42 CFR part 412, subparts A through M.

2. Hospitals and Hospital Units Excluded From the IPPS

Under section 1886(d)(1)(B) of the Act, as amended, certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Inpatient rehabilitation facility (IRF) hospitals and units; long-term care hospitals (LTCHs); psychiatric hospitals and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS. Various sections of the Balanced Budget Act of 1997 (BBA, Pub. L. 105–33), the Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106–113), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106–554) provide for the implementation of PPSs for IRF hospitals and units, LTCHs, and psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)). (We note that the annual updates to the LTCH PPS are included along with the IPPS annual update in this document. Updates to the IRF PPS and IPF PPS are issued as separate documents.) Children's hospitals, cancer hospitals, hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa), and RNHCIs continue to be paid solely under a reasonable cost-based system, subject to a rate-of-increase ceiling on inpatient operating costs. Similarly, extended neoplastic disease care hospitals are paid on a reasonable cost basis, subject to a rate-of-increase ceiling on inpatient operating costs.

The existing regulations governing payments to excluded hospitals and hospital units are located in 42 CFR parts 412 and 413.

3. Long-Term Care Hospital Prospective Payment System (LTCH PPS)

The Medicare prospective payment system (PPS) for LTCHs applies to hospitals described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002. The LTCH PPS was established under the authority of sections 123 of the BBRA and section 307(b) of the BIPA (as codified under section 1886(m)(1) of the Act). Section 1206(a) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) established the site neutral payment rate under the LTCH PPS, which made the LTCH PPS a dual rate payment system beginning in FY 2016. Under this statute, effective for LTCH's cost reporting periods beginning in FY 2016 cost reporting period, LTCHs are generally paid for discharges at the site neutral payment rate unless the discharge meets the patient criteria for payment at the LTCH PPS standard Federal payment rate. The existing regulations governing payment under the LTCH PPS are located in 42 CFR part 412, subpart O. Beginning October 1, 2009, we issue the annual updates to the LTCH PPS in the same documents that update the IPPS.

4. Critical Access Hospitals (CAHs)

Under sections 1814(l), 1820, and 1834(g) of the Act, payments made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services are generally based on 101 percent of reasonable cost. Reasonable cost is determined under the provisions of section 1861(v) of the Act and existing regulations under 42 CFR part 413.

5. Payments for Graduate Medical Education (GME)

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. The amount of payment for direct GME costs for a cost reporting period is based on the hospital's number of residents in that period and the hospital's costs per resident in a base year. The existing regulations governing payments to the various types of hospitals are located in 42 CFR part 413.

C. Summary of Provisions of Recent Legislation That Would Be Implemented in This Proposed Rule

1. Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185)

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185), enacted on October 6, 2014, made a number of changes that affect the Long Term Care Hospital Quality Reporting Program (LTCH QRP). In this proposed rule, there are no proposals or updates to the LTCH Quality Reporting Program. We are continuing to maintain portions of section 1899B of the Act, as added by section 2(a) of the IMPACT Act, which, in part, requires LTCHs, among other post-acute care providers, to report standardized patient assessment data, data on quality measures, and data on resource use and other measures.

2. The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10)

Section 414 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA, Pub. L. 114–10) specifies a 0.5 percent positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. These adjustments follow the recoupment adjustment to the standardized amounts under section 1886(d) of the Act based upon the Secretary's estimates for discharges occurring from FYs 2014 through 2017 to fully offset $11 billion, in accordance with section 631 of the ATRA. The FY 2018 adjustment was subsequently adjusted to 0.4588 percent by section 15005 of the 21st Century Cures Act.

3. Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94)

Section 108 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94) provides that, effective for cost reporting periods beginning on or after October 1, 2020, payment to a subsection (d) hospital that furnishes an allogeneic hematopoietic stem cell transplant for hematopoietic stem cell acquisition shall be made on a reasonable cost basis, and that the Secretary shall specify the items included in such hematopoietic stem cell acquisition in rulemaking. This statutory provision also requires that, beginning in FY 2021, the payments made based on reasonable cost for the acquisition costs of allogeneic hematopoietic stem cells be made in a budget neutral manner.

D. Summary of the Provisions of This Proposed Rule

In this proposed rule, we set forth proposed payment and policy changes to the Medicare IPPS for FY 2021 operating costs and capital-related costs of acute care hospitals and certain hospitals and hospital units that are excluded from IPPS. In addition, we set forth proposed changes to the payment rates, factors, and other payment and policy-related changes to programs associated with payment rate policies under the LTCH PPS for FY 2021.

The following is a general summary of the changes that we are proposing to make in this proposed rule.

1. Proposed Changes to MS–DRG Classifications and Recalibrations of Relative Weights

In section II. of the preamble of this proposed rule, we include—

- Proposed changes to MS–DRG classifications based on our yearly review for FY 2021.
- Proposed adjustment to the standardized amounts under section 1886(d) of the Act for FY 2021 in accordance with the amendments made to section 7(b)(1)(B) of Public Law 110–90 by section 414 of the MACRA.
- Proposed recalibration of the MS–DRG relative weights.
- A discussion of the proposed FY 2021 status of new technologies approved for add-on payments for FY 2020, a presentation of our evaluation and analysis of the FY 2021 applicants for add-on payments for high-cost new medical services and technologies (including public input, as directed by Pub. L. 108–173, obtained in a town hall meeting) for applications not submitted under an alternative pathway, and a discussion of the proposed status of FY 2021 new technology applicants under the alternative pathways for certain medical devices and certain antimicrobial products.
- Proposed revision to the new technology add-on payment policy where the coding associated with an application for new technology add-on payments or a previously approved technology that may continue to receive new technology add-on payments is proposed to be assigned to a proposed new MS–DRG.
- Proposed changes to the timing of the IPPS new technology add-on payment for certain antimicrobial products, and proposed expansion of the alternative pathway for certain antimicrobial products.

2. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

In section III. of the preamble of this proposed rule we propose to make revisions to the wage index for acute care hospitals and the annual update of the wage data. Specific issues addressed include, but are not limited to, the following:

- Proposed changes in the labor market area delineations based on revisions to the OMB Core Based Statistical Area (CBSA) delineations and proposed policies related to the proposed changes in CBSAs.
- The proposed FY 2021 wage index update using wage data from cost reporting periods beginning in FY 2017.
- Calculation, analysis, and implementation of the proposed occupational mix adjustment to the wage index for acute care hospitals for FY 2021 based on the 2016 Occupational Mix Survey.
- Proposed application of the rural floor and the frontier State floor, and continuation of the low wage index hospital policy.
- Proposed revisions to the wage index for acute care hospitals, based on hospital redesignations and reclassifications under sections 1886(d)(8)(B), (d)(8)(E), and (d)(10) of the Act.
- Proposed change to Lugar county assignments.
- Proposed adjustment to the wage index for acute care hospitals for FY 2021 based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index.
- Proposed labor-related share for the proposed FY 2021 wage index.

3. Other Decisions and Proposed Changes to the IPPS for Operating Costs

In section IV. of the preamble of this proposed rule, we discuss proposed changes or clarifications of a number of the provisions of the regulations in 42 CFR parts 412 and 413, including the following:

- Proposed changes to MS–DRGs subject to the post-acute care transfer policy and special payment policy.
- Proposed inpatient hospital update for FY 2021.
- Proposed amendment to address short cost reporting periods during applicable timeframe for establishment of service area for SCHs.
- Proposed updated national and regional case-mix values and discharges for purposes of determining RRC status, and proposed amendment for hospital cost reporting periods that are longer or shorter than 12 months.

- The statutorily required IME adjustment factor for FY 2021.
- Proposed changes to the methodologies for determining Medicare DSH payments and the additional payments for uncompensated care.
- Proposed changes to payment for allogeneic hematopoietic stem cell acquisition costs.
- Proposed payment adjustment for chimeric antigen receptor (CAR) T-cell therapy clinical trial cases.
- Proposed requirements for payment adjustments under the Hospital Readmissions Reduction Program for FY 2021.
- The provision of estimated and newly established performance standards for the calculation of value-based incentive payments under the Hospital Value-Based Purchasing Program.
- Proposed requirements for payment adjustments to hospitals under the HAC Reduction Program for FY 2021.
- Proposed policy changes related to medical residents affected by residency program or teaching hospital closure.
- Discussion of and proposals relating to the implementation of the Rural Community Hospital Demonstration Program in FY 2021.
- Proposal to collect market-based rate information on the Medicare cost report for cost reporting periods ending on or after January 1, 2021, and request for comment on a potential market-based MS–DRG relative weight methodology beginning in FY 2024, that we may adopt in this rulemaking.

4. Proposed FY 2021 Policy Governing the IPPS for Capital-Related Costs

In section V. of the preamble to this proposed rule, we discuss the proposed payment policy requirements for capital-related costs and capital payments to hospitals for FY 2021.

5. Proposed Changes to the Payment Rates for Certain Excluded Hospitals: Rate-of-Increase Percentages

In section VI. of the preamble of this proposed rule, we discuss—
- Proposed changes to payments to certain excluded hospitals for FY 2021.
- Proposed continued implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration.

6. Proposed Changes to the LTCH PPS

In section VII. of the preamble of this proposed rule, we set forth—
- Proposed changes to the LTCH PPS Federal payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2021.
- Proposed rebasing and revising of the LTCH PPS market basket.

7. Proposed Changes Relating to Quality Data Reporting for Specific Providers and Suppliers

In section VIII. of the preamble of this proposed rule, we address—
- Proposed requirements for the Hospital Inpatient Quality Reporting (IQR) Program.
- Proposed changes to the requirements for the quality reporting program for PPS-exempt cancer hospitals (PCHQR Program).
- The FY 2021 requirements under the LTCH Quality Reporting Program (LTCH QRP).
- Proposed changes to requirements pertaining to eligible hospitals and CAHs participating in the Medicare and Medicaid Promoting Interoperability Programs.

8. Other Proposals Included in This Proposed Rule

Section IX. of the preamble to this proposed rule includes the following proposals:
- Proposed changes pertaining to the submission format requirements and reimbursement rates for patient records sent to the Beneficiary and Family Centered Care Quality Improvement Organizations (BFCC–QIOs).
- Proposed changes pertaining to allowing for mandatory electronic filing of Provider Reimbursement Review Board appeals.
- Proposed changes pertaining to and codification of certain longstanding Medicare Bad Debt policies.

9. Other Provisions of This Proposed Rule

Section X. of the preamble preamble to this proposed rule includes our discussion of the MedPAC Recommendations.

Section XI. of the preamble to this proposed rule includes the following:
- A descriptive listing of the public use files associated with the proposed rule.
- The collection of information requirements for entities based on our proposals.
- Information regarding our responses to public comments.
- Waiver of the 60-day delay in effective date for the final rule.

10. Determining Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals

In sections II. and III. of the Addendum to the proposed rule, we set forth the proposed changes to the amounts and factors for determining the proposed FY 2021 prospective payment rates for operating costs and capital-related costs for acute care hospitals. We are proposing to establish the threshold amounts for outlier cases. In addition, in section IV. of the Addendum to the proposed rule, we address the update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2021 for certain hospitals excluded from the IPPS.

11. Determining Prospective Payment Rates for LTCHs

In section V. of the Addendum to the proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2021 LTCH PPS standard Federal payment rate and other factors used to determine LTCH PPS payments under both the LTCH PPS standard Federal payment rate and the site neutral payment rate in FY 2021. We are proposing to establish the adjustment for wage levels, including the proposed changes in the CBSAs based on revisions to the OMB labor market area delineations and a proposed adjustment to reflect the expected increases in wages under the IPPS low wage index hospital policy. We are proposing to establish the adjustments for the labor-related share, the cost-of-living adjustment, and high-cost outliers, including the applicable fixed-loss amounts and the LTCH cost-to-charge ratios (CCRs) for both payment rates.

12. Impact Analysis

In Appendix A of this proposed rule, we set forth an analysis of the impact the proposed changes would have on affected acute care hospitals, CAHs, LTCHs, PCHs and other entities.

13. Recommendation of Update Factors for Operating Cost Rates of Payment for Hospital Inpatient Services

In Appendix B of the proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provide our recommendations of the appropriate percentage changes for FY 2021 for the following:
- A single average standardized amount for all areas for hospital inpatient services paid under the IPPS for operating costs of acute care hospitals (and hospital-specific rates applicable to SCHs and MDHs).
- Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by certain hospitals excluded from the IPPS.
- The LTCH PPS standard Federal payment rate and the site neutral payment rate for hospital inpatient

services provided for LTCH PPS discharges.

14. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, MedPAC is required to submit a report to Congress, no later than March 15 of each year, in which MedPAC reviews and makes recommendations on Medicare payment policies. MedPAC's March 2020 recommendations concerning hospital inpatient payment policies address the update factor for hospital inpatient operating costs and capital-related costs for hospitals under the IPPS. We address these recommendations in Appendix B of this proposed rule. For further information relating specifically to the MedPAC March 2020 report or to obtain a copy of the report, contact MedPAC at (202) 220–3700 or visit MedPAC's website at: *http://www.medpac.gov*.

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. The Office of the National Coordinator for Health Information Technology (ONC) and CMS work collaboratively to advance interoperability across settings of care, including post-acute care.

To further interoperability in across all care settings, CMS continues to explore opportunities to advance electronic exchange of patient information across payers, providers and with patients, including developing systems that use nationally recognized health IT standards such as Logical Observation Identifier Names and Codes (LOINC), Systemized Nomenclature of Medicine-Clinical Terms (SNOMED), and Fast Healthcare Interoperability Recourses (FHIR). In addition, CMS and ONC are collaborating with industry stakeholders via the Post-Acute Care Interoperability Workgroup (PACIO) (to develop FHIR-based standards for post-acute care (PAC) assessment content, which could support the exchange and reuse of patient *http://pacioproject.org/*) 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 Data Set (LTCH CARE data set), Outcome Assessment Information Set (OASIS) assessment tools, and other sources. The Data Element Library (DEL) (*https://del.cms.gov/DELWeb/pubHome*) continues to be updated and serves as the authoritative resource for PAC assessment data elements and their associated mappings to health IT standards. These interoperable data elements can reduce provider burden by allowing the use and exchange of healthcare data, support provider exchange of electronic health information for care coordination, person-centered care, and support real-time, data driven, clinical decision-making. Standards in the DEL (*https://del.cms.gov/*) can be referenced on the CMS website and in the ONC Interoperability Standards Advisory (ISA). The 2020 ISA is available at *https://www.healthit.gov/isa*.

In the September 30, 2019 **Federal Register**, we published a final rule titled, ''Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies, and Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care'' (84 FR 51836) (''Discharge Planning final rule''), that revises the discharge planning requirements that hospitals (including psychiatric hospitals, long-term care hospitals, and inpatient rehabilitation facilities), critical access hospitals (CAHs), and home health agencies, must meet to participate in Medicare and Medicaid programs. It also revises one provision regarding patient rights in hospitals. The rule supports our interoperability efforts by promoting the exchange of patient information between health care settings, and by ensuring that a patient's necessary medical information is transferred with the patient after discharge from a hospital, CAH, or post-acute care services provider. For more information on the discharge planning requirements, please visit the final rule at: *https://www.federalregister.gov/documents/2019/09/30/2019-20732/medicare-and-medicaid-programs-revisions-to-requirements-for-discharge-planning-for-hospitals*.

We invite providers to learn more about these important developments and how they are likely to affect LTCHs and encourage the electronic exchange of health data across care settings and with patients.

II. Proposed Changes to Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications and Relative Weights

A. Background

Section 1886(d) of the Act specifies that the Secretary shall establish a classification system (referred to as diagnosis-related groups (DRGs)) for inpatient discharges and adjust payments under the IPPS based on appropriate weighting factors assigned to each DRG. (Beginning in FY 2008, CMS adopted the Medicare-Severity DRGs (MS–DRGs) to better recognize severity of illness and resource use based on case complexity.) Therefore, under the IPPS, Medicare pays for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG, relative to the average resources used to treat cases in all DRGs.

Section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually to account for changes in resource consumption. These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources.

B. Adoption of the MS–DRGs and MS–DRG Reclassifications

For information on the adoption of the MS–DRGs in FY 2008, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189).

For general information about the MS–DRG system, including yearly reviews and changes to the MS–DRGs, we refer readers to the previous discussions in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43764 through 43766) and the FYs 2011 through 2020 IPPS/LTCH PPS final rules (75 FR 50053 through 50055; 76 FR 51485 through 51487; 77 FR 53273; 78 FR 50512; 79 FR 49871; 80 FR 49342; 81 FR 56787 through 56872; 82 FR 38010 through 38085, 83 FR 41158 through 41258, and 84 FR 42058 through 42165, respectively).

C. Proposed FY 2021 MS–DRG Documentation and Coding Adjustment

1. Background on the Prospective MS–DRG Documentation and Coding Adjustments for FY 2008 and FY 2009 Authorized by Public Law 110–90 and the Recoupment or Repayment Adjustment Authorized by Section 631 of the American Taxpayer Relief Act of 2012 (ATRA)

In the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189), we adopted the MS–DRG patient classification system for the IPPS, effective October 1, 2007, to better recognize severity of illness in Medicare payment rates for acute care hospitals. The adoption of the MS–DRG system resulted in the expansion of the number of DRGs from 538 in FY 2007 to 745 in FY 2008. By increasing the number of MS–DRGs and more fully taking into account patient severity of illness in Medicare payment rates for acute care hospitals, MS–DRGs encourage hospitals to improve their documentation and coding of patient diagnoses.

In the FY 2008 IPPS final rule with comment period (72 FR 47175 through 47186), we indicated that the adoption of the MS–DRGs had the potential to lead to increases in aggregate payments without a corresponding increase in actual patient severity of illness due to the incentives for additional documentation and coding. In that final rule with comment period, we exercised our authority under section 1886(d)(3)(A)(vi) of the Act, which authorizes us to maintain budget neutrality by adjusting the national standardized amount, to eliminate the estimated effect of changes in coding or classification that do not reflect real changes in case-mix. Our actuaries estimated that maintaining budget neutrality required an adjustment of −4.8 percentage points to the national standardized amount. We provided for phasing in this −4.8 percentage point adjustment over 3 years. Specifically, we established prospective documentation and coding adjustments of −1.2 percentage points for FY 2008, −1.8 percentage points for FY 2009, and −1.8 percentage points for FY 2010.

On September 29, 2007, Congress enacted the TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007 (Pub. L. 110–90). Section 7(a) of Public Law 110–90 reduced the documentation and coding adjustment made as a result of the MS–DRG system that we adopted in the FY 2008 IPPS final rule with comment period to −0.6 percentage point for FY 2008 and −0.9 percentage point for FY 2009.

As discussed in prior year rulemakings, and most recently in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56780 through 56782), we implemented a series of adjustments required under sections 7(b)(1)(A) and 7(b)(1)(B) of Public Law 110–90, based on a retrospective review of FY 2008 and FY 2009 claims data. We completed these adjustments in FY 2013 but indicated in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53274 through 53275) that delaying full implementation of the adjustment required under section 7(b)(1)(A) of Public Law 110–90 until FY 2013 resulted in payments in FY 2010 through FY 2012 being overstated, and that these overpayments could not be recovered under Public Law 110–90.

In addition, as discussed in prior rulemakings and most recently in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38008 through 38009), section 631 of the American Taxpayer Relief Act of 2012 (ATRA) amended section 7(b)(1)(B) of Public Law 110–90 to require the Secretary to make a recoupment adjustment or adjustments totaling $11 billion by FY 2017. This adjustment represented the amount of the increase in aggregate payments as a result of not completing the prospective adjustment authorized under section 7(b)(1)(A) of Public Law 110–90 until FY 2013.

2. Adjustments Made for FY 2018, FY 2019, and FY 2020 as Required Under Section 414 of Public Law 114–10 (MACRA) and Section 15005 of Public Law 114–255

As stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56785), once the recoupment required under section 631 of the ATRA was complete, we had anticipated making a single positive adjustment in FY 2018 to offset the reductions required to recoup the $11 billion under section 631 of the ATRA. However, section 414 of the MACRA (which was enacted on April 16, 2015) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percentage point positive adjustment for each of FYs 2018 through 2023. In the FY 2017 rulemaking, we indicated that we would address the adjustments for FY 2018 and later fiscal years in future rulemaking. Section 15005 of the 21st Century Cures Act (Pub. L. 114–255), which was enacted on December 13, 2016, amended section 7(b)(1)(B) of the TMA, as amended by section 631 of the ATRA and section 414 of the MACRA, to reduce the adjustment for FY 2018 from a 0.5 percentage point positive adjustment to a 0.4588 percentage point positive adjustment. As we discussed in the FY 2018 rulemaking, we believe the directive under section 15005 of Public Law 114–255 is clear. Therefore, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38009) for FY 2018, we implemented the required +0.4588 percentage point adjustment to the standardized amount. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41157) and in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42057), consistent with the requirements of section 414 of the MACRA, we implemented 0.5 percentage point positive adjustments to the standardized amount for FY 2019 and FY 2020, respectively. We indicated that the FY 2018, FY 2019, and FY 2020 adjustments were permanent adjustments to payment rates. We also stated that we plan to propose future adjustments required under section 414 of the MACRA for FYs 2021 through 2023 in future rulemaking.

3. Proposed Adjustment for FY 2021

Consistent with the requirements of section 414 of the MACRA, we are proposing to implement a 0.5 percentage point positive adjustment to the standardized amount for FY 2021. This would constitute a permanent adjustment to payment rates. We plan to propose future adjustments required under section 414 of the MACRA for FYs 2022 through 2023 in future rulemaking.

D. Proposed Changes to Specific MS–DRG Classifications

1. Discussion of Changes to Coding System and Basis for Proposed FY 2021 MS–DRG Updates

a. Conversion of MS–DRGs to the International Classification of Diseases, 10th Revision (ICD–10)

As of October 1, 2015, providers use the International Classification of Diseases, 10th Revision (ICD–10) coding system to report diagnoses and procedures for Medicare hospital inpatient services under the MS–DRG system instead of the ICD–9–CM coding system, which was used through September 30, 2015. The ICD–10 coding system includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, as well as the ICD–10–CM and ICD–10–PCS Official Guidelines for Coding and

Reporting. For a detailed discussion of the conversion of the MS–DRGs to ICD–10, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787 through 56789).

b. Basis for Proposed FY 2021 MS–DRG Updates

Given the need for more time to carefully evaluate requests and propose updates, as discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38010), we changed the deadline to request updates to the MS–DRGs to November 1 of each year, which provided an additional 5 weeks for the data analysis and review process. Interested parties had to submit any comments and suggestions for FY 2021 by November 1, 2019, and the comments that were submitted in a timely manner for FY 2021 are discussed in this section of the preamble of this proposed rule. As we discuss in the sections that follow, we may not be able to fully consider all of the requests that we receive for the upcoming fiscal year. We have found that, with the implementation of ICD–10, some types of requested changes to the MS–DRG classifications require more extensive research to identify and analyze all of the data that are relevant to evaluating the potential change. We note in the discussion that follows those topics for which further research and analysis are required, and which we will continue to consider in connection with future rulemaking.

With the continued increase in the number and complexity of the requested changes to the MS–DRG classifications since the adoption of ICD–10 MS–DRGs, and in order to consider as many requests as possible, more time is needed to carefully evaluate the requested changes, analyze claims data, and consider any proposed updates. Therefore, we are changing the deadline to request changes to the MS–DRGs to October 20th of each year to allow for additional time for the review and consideration of any proposed updates. Interested parties should submit any comments and suggestions for FY 2022 by October 20, 2020 via the CMS MS–DRG Classification Change Request Mailbox located at: *MSDRGClassificationChange@cms.hhs.gov*.

Based on public comments received in response to the FY 2020 IPPS/LTCH PPS proposed rule, we are providing a test version of the ICD–10 MS–DRG GROUPER Software, Version 38, so that the public can better analyze and understand the impact of the proposals included in this proposed rule. We note that this test software reflects the proposed GROUPER logic for FY 2021. Therefore, it includes the new diagnosis and procedure codes that are effective for FY 2021 as reflected in Table 6A.—New Diagnosis Codes—FY 2021 and Table 6B.—New Procedure Codes—FY 2021 associated with this proposed rule and does not include the diagnosis codes that are invalid beginning in FY 2021 as reflected in Table 6C.—Invalid Diagnosis Codes—FY 2021 associated with this proposed rule. We note that there are not any procedure codes that have been designated as invalid for FY 2021 at the time of the development of this proposed rule. These tables are not published in the Addendum to this proposed rule, but are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as described in section VI. of the Addendum to this proposed rule. Because the diagnosis codes no longer valid for FY 2021 are not reflected in the test software, we are making available a supplemental file in Table 6P.1a that includes the mapped Version 38 FY 2021 ICD–10–CM codes and the deleted Version 37 FY 2020 ICD–10–CM codes that should be used for testing purposes with users' available claims data. Therefore, users will have access to the test software allowing them to build case examples that reflect the proposals included in this proposed rule. In addition, users will be able to view the draft version of the ICD–10 MS–DRG Definitions Manual, Version 38.

The test version of the ICD–10 MS–DRG GROUPER Software, Version 38, the draft version of the ICD–10 MS–DRG Definitions Manual, Version 38, and the supplemental mapping file in Table 6P.1a of FY 2020 and FY 2021 ICD–10–CM diagnosis codes are available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

Following are the changes that we are proposing to the MS–DRGs for FY 2021. We are inviting public comments on each of the MS–DRG classification proposed changes, as well as our proposals to maintain certain existing MS–DRG classifications discussed in this proposed rule. In some cases, we are proposing changes to the MS–DRG classifications based on our analysis of claims data and consultation with our clinical advisors. In other cases, we are proposing to maintain the existing MS–DRG classifications based on our analysis of claims data and consultation with our clinical advisors. For this FY 2021 IPPS/LTCH PPS proposed rule, our MS–DRG analysis was based on ICD–10 claims data from the September 2019 update of the FY 2019 MedPAR file, which contains hospital bills received through September 30, 2019, for discharges occurring through September 30, 2019. In our discussion of the proposed MS–DRG reclassification changes, we refer to these claims data as the ''September 2019 update of the FY 2019 MedPAR file.''

As explained in previous rulemaking (76 FR 51487), in deciding whether to propose to make further modifications to the MS–DRGs for particular circumstances brought to our attention, we consider whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients represented in the MS–DRG. We evaluate patient care costs using average costs and lengths of stay and rely on the judgment of our clinical advisors to determine whether patients are clinically distinct or similar to other patients represented in the MS–DRG. In evaluating resource costs, we consider both the absolute and percentage differences in average costs between the cases we select for review and the remainder of cases in the MS–DRG. We also consider variation in costs within these groups; that is, whether observed average differences are consistent across patients or attributable to cases that are extreme in terms of costs or length of stay, or both. Further, we consider the number of patients who will have a given set of characteristics and generally prefer not to create a new MS–DRG unless it would include a substantial number of cases.

In our examination of the claims data, we apply the following criteria established in FY 2008 (72 FR 47169) to determine if the creation of a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS–DRG is warranted:

- A reduction in variance of costs of at least 3 percent;
- At least 5 percent of the patients in the MS–DRG fall within the CC or MCC subgroup;
- At least 500 cases are in the CC or MCC subgroup;
- There is at least a 20-percent difference in average costs between subgroups; and
- There is a $2,000 difference in average costs between subgroups.

In order to warrant creation of a CC or MCC subgroup within a base MS–DRG, the subgroup must meet all five of the criteria.

Beginning with this FY 2021 IPPS/LTCH PPS proposed rule, we are proposing to expand the previously

listed criteria to also include the NonCC subgroup. We believe that applying these criteria to the NonCC subgroup would better reflect resource stratification and also promote stability in the relative weights by avoiding low volume counts for the NonCC level MS–DRGs.

Specifically, in our analysis of the MS–DRG classification requests for FY 2021 that we received by November 1, 2019, as well as any additional analyses that were conducted in connection with those requests, we applied these criteria to each of the MCC, CC and NonCC subgroups, as described in the following table. We are providing the following table to better illustrate all five criteria and how they are applied for each CC subgroup, including their application to the NonCC subgroup beginning with this FY 2021 proposed rule. We have revised the order in which the criteria are presented for illustrative purposes.

Criteria Number	Three-Way Split 123 (MCC vs CC vs NonCC)	Two-Way Split 1_23 MCC vs (CC+NonCC)	Two-Way Split 12_3 (MCC+CC) vs NonCC
1. At least 500 cases in the MCC/CC/NonCC group	500+ cases for MCC group; and 500+ cases for CC group; and 500+ cases for NonCC group	500+ cases for MCC group; and 500+ cases for (CC+NonCC) group	500+ cases for (MCC+CC) group; and 500+ cases for NonCC group
2. At least 5% of the patients are in the MCC/CC/NonCC group	5%+ cases for MCC group; and 5%+ cases for CC group; and 5%+ cases for NonCC group	5%+ cases for MCC group; and 5%+ cases for (CC+NonCC) group	5%+ cases for (MCC+CC) group; and 5%+ cases for NonCC group
3. There is at least a 20% difference in average cost between subgroups	20%+ difference in average cost between MCC group and CC group; and 20%+ difference in average cost between CC group and NonCC group	20%+ difference in average cost between MCC group and (CC+NonCC) group	20%+ difference in average cost between (MCC+ CC) group and NonCC group
4. There is at least a $2,000 difference in average cost between subgroups	$2,000+ difference in average cost between MCC group and CC group; and $2,000+ difference in average cost between CC group and NonCC group	$2,000+ difference in average cost between MCC group and (CC+ NonCC) group	$2,000+ difference in average cost between (MCC+ CC) group and NonCC group
5. The R2 of the split groups is greater than or equal to 3	R2 > 3.0 for the three way split within the base MS-DRG	R2 > 3.0 for the two way 1_23 split within the base MS-DRG	R2 > 3.0 for the two way 12_3 split within the base MS-DRG

In general, once the decision has been made to propose to make further modifications to the MS–DRGs as described previously, such as creating a new base MS–DRG, or in our evaluation of a specific MS–DRG classification request to split (or subdivide) an existing base MS–DRG into severity levels, all five criteria must be met for the base MS–DRG to be split (or subdivided) by a CC subgroup. We note that in our analysis of requests to create a new MS–DRG, we evaluate the most recent year of MedPAR claims data available. For example, we stated earlier that for this FY 2021 IPPS/LTCH PPS proposed rule, our MS–DRG analysis was based on ICD–10 claims data from the September 2019 update of the FY 2019 MedPAR file. However, in our evaluation of requests to split an existing base MS–DRG into severity levels, as noted in prior rulemaking (80 FR 49368), we analyze the most recent 2 years of data. This analysis includes 2 years of MedPAR claims data to compare the data results from 1 year to the next to avoid making determinations about whether additional severity levels are warranted based on an isolated year's data fluctuation and also, to validate that the established severity levels within a base MS–DRG are supported. The first step in our process of evaluating if the creation of a new CC subgroup within a base MS–DRG is warranted is to determine if all the criteria are satisfied for a three way split. If the criteria fail, the next step is to determine if the criteria are satisfied for a two way split. If the criteria for both of the two way splits fail, then a split (or CC subgroup) would generally not be warranted for that base MS–DRG. If the three way split fails on any one of the five criteria and all five criteria for both two way splits (1_23 and 12_3) are met, we would apply the two way split with the highest R2 value. We note that if the request to split (or subdivide) an existing base MS–DRG into severity levels specifies the request is for either one of the two way splits (1_23 or 12_3), in response to the specific request, we will evaluate the criteria for both of the two way splits, however we do not also evaluate the criteria for a three way split.

2. Pre-MDC

a. Bone Marrow Transplants

We received two separate requests that involve the MS–DRGs where bone marrow transplant procedures are assigned. The first request was to redesignate MS–DRG 014 (Allogeneic Bone Marrow Transplant), MS–DRG 016 (Autologous Bone Marrow Transplant with CC/MCC or T-Cell Immunotherapy), and MS–DRG 017 (Autologous Bone Marrow Transplant without CC/MCC) from surgical MS–DRGs to medical MS–DRGs. According to the requestor, bone marrow transplant procedures involve a transfusion of donor cells and do not involve a surgical procedure or require the resources of an operating room (O.R.). The second request involving bone marrow transplant procedures was to split MS–DRG 014 (Allogeneic Bone Marrow Transplant) into two severity levels, based on the presence of a MCC. In this section of this rule, we discuss each request in more detail.

With regard to the first request, the requestor noted that the logic for MS–DRG 014 consists of ICD–10–PCS procedure codes describing allogeneic bone marrow transplants that are designated as non-operating room (non-O.R.) procedures. The requestor also noted that the logic for MS–DRGs 016 and 017 includes ICD–10–PCS procedure codes describing autologous bone marrow transplants where certain

procedure codes are designated as O.R. and other procedure codes are designated as non-O.R. procedures. The requestor stated that redesignating the bone marrow transplant MS–DRGs from surgical to medical would clinically align with the resources utilized in the performance of these procedures.

The requestor is correct that bone marrow transplant procedures are currently assigned to MS–DRGs 014, 016, and 017 which are classified as surgical MS–DRGs under the Pre-MDC category for the ICD–10 MS–DRGs. The requestor is also correct that the logic for MS–DRG 014 consists of ICD–10–PCS procedure codes describing allogeneic bone marrow transplants that are designated as non-operating room (non-O.R.) procedures and that the logic for MS–DRGs 016 and 017 includes ICD–10–PCS procedure codes describing autologous bone marrow transplants where certain procedure codes are designated as O.R. procedures and other procedure codes are designated as non-O.R. procedures. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 37 which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for MS–DRGs 014, 016, and 017.

We consulted with our clinical advisors and they agreed that bone marrow transplant procedures are similar to a blood transfusion procedure, do not utilize the resources of an operating room, and are not surgical procedures. Our clinical advisors concurred that bone marrow transplants are medical procedures and it is more accurate to designate the MS–DRGs to which these procedures are assigned as medical MS–DRGs versus surgical MS–DRGs. Therefore, we are proposing to redesignate MS–DRGs 014, 016, and 017 as medical MS–DRGs effective October 1, 2020 for FY 2021.

As noted previously, the logic for MS–DRGs 016 and 017 includes ICD–10–PCS procedure codes describing autologous bone marrow transplants and related procedures where certain procedure codes are designated as O.R. and other procedure codes are designated as non-O.R. procedures. During our review of the bone marrow transplant procedures assigned to these MS–DRGs we identified the following 8 procedure codes that are currently designated as O.R procedures.

ICD-10-PCS Code	Code Description
30230AZ	Transfusion of embryonic stem cells into peripheral vein, open approach
30230G0	Transfusion of autologous bone marrow into peripheral vein, open approach
30230X0	Transfusion of autologous cord blood stem cells into peripheral vein, open approach
30230Y0	Transfusion of autologous hematopoietic stem cells into peripheral vein, open approach
30240AZ	Transfusion of embryonic stem cells into central vein, open approach
30240G0	Transfusion of autologous bone marrow into central vein, open approach
30240X0	Transfusion of autologous cord blood stem cells into central vein, open approach
30240Y0	Transfusion of autologous hematopoietic stem cells into central vein, open approach

In connection with our proposal to designate the MS–DRGs to which these procedures are assigned as medical, as well as for clinical consistency with the other procedure codes describing bone marrow transplant procedures, we are proposing to redesignate the listed ICD–10–PCS procedure codes from O.R. to non-O.R. procedures, affecting their current MS–DRG assignment for MS–DRGs 016 and 017, effective October 1, 2020 for FY 2021.

As noted earlier in this section, we also received a request to split MS–DRG 014 (Allogeneic Bone Marrow Transplant) into two severity levels, based on the presence of a MCC. For FY 2020, the requestor had requested that MS–DRG 014 be split into two new MS–DRGs according to donor source. For the reasons discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19176 through 19180) and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42067 through 42072), we did not propose to split MS–DRG 014 into two new MS–DRGs according to donor source. However, according to the requestor, a single (base) MS–DRG for allogeneic bone marrow and stem cell transplants continues to not be as clinically or resource homogeneous as it could be. The requestor conducted its own analysis and stated the results revealed it was appropriate to split MS–DRG 014 based on the presence of a MCC.

We examined claims data from the September 2019 update of the FY 2019 MedPAR file for MS–DRG 014. There were 962 cases found in MS–DRG 014 with an average length of stay of 26.7 days and average costs of $89,586.

Consistent with our established process, we conducted an analysis of MS–DRG 014 to determine if the criteria to create subgroups were met. The process for conducting this type of analysis includes examining 2 years of MedPAR claims data to compare the data results from 1 year to the next to avoid making determinations about whether additional severity levels are warranted based on an isolated year's data fluctuation and also, to validate that the established severity levels within a base MS–DRG are supported. Therefore, we reviewed the claims data for base MS–DRG 014 using the September 2018 update of the FY 2018 MedPAR file and the September 2019 update of the FY 2019 MedPAR file, which were used in our analysis of claims data for MS–DRG reclassification requests for FY 2020 and FY 2021. Our findings are shown in the table.

FY Data	Number of Cases	Number of Cases MCC	Number of Cases CC	Number of Cases Non CC	Average Costs No Split	Average Costs MCC	Average Costs CC	Average Costs Non CC	Average Costs MCC/CC combo	Average Costs CC/NonCC combo
2019	962	779	141	42	$89,586	$94,840	$69,287	$60,277	$90,924	$67,219
2018	982	807	140	35	$90,759	$95,075	$69,785	$75,157	$91,336	$70,859

We applied the criteria to create subgroups for each of the two-way severity level splits. As discussed in section II.D.1.b., beginning with this FY 2021 IPPS/LTCH PPS proposed rule, we are proposing to expand the previously listed criteria to also include the NonCC group. The criterion that there be at least 500 cases for each subgroup failed due to low volume, as shown in the table for both years. Specifically, for the ''with MCC'' and ''without MCC'' (CC+NonCC) split, there were only 183 (141+42) cases in the ''without MCC'' subgroup based on the data in the FY 2019 MedPAR file and only 175 (140+35) cases in the ''without MCC'' subgroup based on the data in the FY 2018 MedPAR file. For the ''with CC/MCC'' and ''without CC/MCC'' (NonCC) split, there were only 42 cases in the NonCC subgroup based on the data in the FY 2019 MedPAR file and only 35 cases in the NonCC subgroup based on the data in the FY 2018 MedPAR file. The claims data do not support a two-way severity level split for MS–DRG 014, therefore, we are proposing to maintain the current structure of MS–DRG 014 for FY 2021.

b. Chimeric Antigen Receptor (CAR) T-Cell Therapies

We received several requests to create a new MS–DRG for procedures involving CAR T-cell therapies. The requestors stated that creation of a new MS–DRG would improve payment for CAR T-cell therapies in the inpatient setting. Some requestors noted that cases involving CAR T-cell therapies will no longer be eligible for new technology add-on payments in FY 2021 and that this would significantly reduce the overall payment for cases involving CAR T-cell therapies. Some requestors also noted that in the absence of the creation of a new MS–DRG for procedures involving CAR T-cell therapies, outlier payments for these cases would increase significantly, which would increase the share of total outlier payments that are attributable to CAR T-cell therapies.

The requestors stated that the new MS–DRG for CAR T-cell therapies should include cases that report ICD–10–PCS procedure codes XW033C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3) or XW043C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3).

Given the high cost of the CAR T-cell product, some requestors provided recommendations related to the differential treatment of cases where the CAR T-cell product was provided without cost as part of a clinical trial to ensure that the payment amount for the newly created MS–DRG for CAR T-cell therapy cases would appropriately reflect the average cost hospitals incur for providing CAR T-cell therapy outside of a clinical trial. For example, some requestors suggested that CMS make minor adjustments to its usual ratesetting methodology to exclude clinical trial claims from the calculation of the relative weight for any MS–DRG for CAR T-cell therapies. One requestor noted that these adjustments are consistent with CMS' general authority under sections 1886(d)(4)(B) and (C) of the Act. Some requestors also suggested that CMS apply an offset to the MS–DRG payment in cases where the provider does not incur the cost of the CAR T-cell therapy.

Currently, procedures involving CAR T-cell therapies are identified with ICD–10–PCS procedure codes XW033C3 and XW043C3, which became effective October 1, 2017. In the FY 2019 IPPS/LTCH PPS final rule, we finalized our proposal to assign cases reporting these ICD–10–PCS procedure codes to Pre-MDC MS–DRG 016 for FY 2019 and to revise the title of this MS–DRG to ''Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy''. We refer readers to section II.F.2.d. of the preamble of the FY 2019 IPPS/LTCH PPS final rule for a complete discussion of these final policies (83 FR 41172 through 41174).

As noted, the current procedure codes for CAR T-cell therapies both became effective October 1, 2017. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41172 through 41174), we indicated that we believed we should collect more comprehensive clinical and cost data before considering assignment of a new MS–DRG to these therapies. We stated in the FY 2020 IPPS/LTCH PPS proposed rule that, while the September 2018 update of the FY 2018 MedPAR data file does contain some claims that include those procedure codes that identify CAR T-cell therapies, the number of cases is limited, and the submitted costs vary widely due to differences in provider billing and charging practices for this therapy. Therefore, while those claims could potentially be used to create relative weights for a new MS–DRG, we stated that we did not have the comprehensive clinical and cost data that we generally believe are needed to do so. Furthermore, we stated in the FY 2020 IPPS/LTCH PPS proposed rule that given the relative newness of CAR T-cell therapy and our proposal to continue new technology add-on payments for FY 2020 for the two CAR T-cell therapies that currently have FDA approval (KYMRIAH™ and YESCARTA™), at the time we believed it was premature to consider creation of a new MS–DRG specifically for cases involving CAR T-cell therapy for FY 2020. We stated that in future years we would have additional data that could be used to evaluate the potential creation of a new MS–DRG specifically for cases involving CAR T-cell therapies.

We now have more data upon which to evaluate a new MS–DRG specifically for cases involving CAR T-cell therapies. We agree with the requestors it is appropriate to consider the development of a new MS–DRG using the data that is now available. We examined the claims data from the September 2019 update of the FY 2019 MedPAR data file for cases that reported ICD–10–PCS procedure codes XW033C3 or XW043C3. For purposes of this analysis, we identified clinical trial cases as claims with ICD–10–CM diagnosis code Z00.6 (Encounter for examination for normal comparison and control in clinical research program) which is reported only for clinical trial cases, or with standardized drug charges of less than $373,000, which is the average sales price of KYMRIAH and YESCARTA, which are the two CAR T-cell medicines approved to treat relapsed/refractory diffuse large B-cell lymphoma as of the time of the

development of this proposed rule. We distinguished between clinical trial and non-clinical trial cases in this analysis because we agree with the requestors who indicated that given the high cost of the CAR T-cell product, it is appropriate to distinguish cases where the CAR T-cell product was provided without cost as part of a clinical trial so that the analysis appropriately reflects the resources required to provide CAR T-cell therapy outside of a clinical trial. We also note that we included cases that would have been identified as statistical outliers under our usual process when examined as part of MS–DRG 016 due to the extreme cost differences between the CAR T-cell therapy claims and other claims in MS–DRG 016, but would not be identified as statistical outliers when examining CAR T-cell therapy claims only. Our findings are shown in the table.

MS-DRG	Description		Number of Cases	Average Length of Stay	Average Costs
016	All Cases		2,212	18.2	$55,001
	ICD-10-PCS codes XW033C3 or XW043C3	All cases	262	16.3	$127,408
		Non-clinical trial cases	94	17.2	$274,952
		Clinical trial cases	168	15.8	$44,853

*We note that we included 18 cases that were flagged as statistical outliers in our trim methodology due to the mix of CAR T- cell therapy and non-CAR T - cell therapy cases in the current MS-DRG.

As shown in the table, we found 2,212 cases in MS–DRG 016, with an average length of stay of 18.2 days and average costs of $55,001. Of these 2,212 cases, 262 cases reported ICD–10–PCS procedure codes XW033C3 or XW043C3; these cases had an average length of stay of 16.3 days and average costs of $127,408. Of these 262 cases, 94 were identified as non-clinical trial cases; these cases had an average length of stay of 17.2 days and average costs of $274,952. The remaining 168 cases were identified as clinical trial cases; these cases had an average length of stay of 15.8 days and average costs of $44,853.

The data indicate that the average costs for the non-clinical trial cases that reported ICD–10–PCS procedure codes XW033C3 or XW043C3 are almost five times higher than the average costs for all cases in MS–DRG 016. Our clinical advisors also believe that the cases reporting ICD–10–PCS procedure codes XW033C3 or XW043C3 can be clinically differentiated from other cases that group to MS–DRG 016, which includes procedures involving autologous bone marrow transplants, once the CAR T-cell therapy itself is taken into account in the comparison.

As described earlier in this section, in deciding whether to propose to make modifications to the MS–DRGs for particular circumstances brought to our attention, we consider a variety of factors pertaining to resource consumption and clinical characteristics. While we generally prefer not to create a new MS–DRG unless it would include a substantial number of cases, our clinical advisors believe that the vast discrepancy in resource consumption as reflected in the claims data analysis and the clinical differences warrant the creation of a new MS–DRG. We are therefore proposing to assign cases reporting ICD–10–PCS procedure codes XW033C3 or XW043C3 to a proposed new MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy). If additional procedure codes describing CAR–T cell therapies are approved and finalized, we would use our established process to assign these procedure codes to the most appropriate MS–DRG. Because these cases would no longer group to MS–DRG 016, we are proposing to revise the title for MS–DRG 016 from ''Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy'' to ''Autologous Bone Marrow Transplant with CC/MCC.'' We refer readers to section II.E.2.b. of the preamble of this proposed rule for a discussion of the proposed relative weight calculation for the proposed new MS–DRG 018 for CAR T-cell Therapy, and to section IV.I. of the preamble of this proposed rule for a discussion of the proposed payment adjustment for CAR T-cell clinical trial cases.

3. MDC 1 (Diseases and Disorders of the Nervous System)

a. Carotid Artery Stent Procedures

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42078), we finalized our proposal to reassign 96 ICD–10–PCS procedure codes describing dilation of carotid artery with an intraluminal device(s) from MS–DRGs 037, 038, and 039 (Extracranial Procedures with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 034, 035, and 036 (Carotid Artery Stent Procedures with MCC, with CC, and without CC/MCC, respectively). We received a request to review six ICD–10–PCS procedure codes describing dilation of a carotid artery (common, internal or external) with drug eluting intraluminal devices(s) using an open approach that are currently assigned to the logic for case assignment to MS–DRGs 037, 038, and 039 that were not included in the list of codes finalized for reassignment in the FY 2020 IPPS/LTCH PPS final rule. The six codes are identified in the following table.

ICD-10-PCS Code	Code Description
037H04Z	Dilation of right common carotid artery with drug-eluting intraluminal device, open approach
037J04Z	Dilation of left common carotid artery with drug-eluting intraluminal device, open approach
037K04Z	Dilation of right internal carotid artery with drug-eluting intraluminal device, open approach
037L04Z	Dilation of left internal carotid artery with drug-eluting intraluminal device, open approach
037M04Z	Dilation of right external carotid artery with drug-eluting intraluminal device, open approach
037N04Z	Dilation of left external carotid artery with drug-eluting intraluminal device, open approach

The logic for case assignment to MS–DRGs 034, 035, and 036 as displayed in the ICD–10 MS–DRG Version 37 Definitions Manual, available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html* is comprised of a list of logic which includes procedure codes for operating room procedures involving dilation of a carotid artery (common, internal or external) with intraluminal device(s). All of the ICD–10–PCS procedure codes in the logic list assigned to MS–DRGs 034, 035, and 036 describe dilation of a carotid artery with an intraluminal device.

We examined claims data from the September 2019 update of the FY 2019 MedPAR file for MS–DRGs 034, 035, and 036 which only include those procedure codes that describe procedures that involve dilation of a carotid artery with an intraluminal device. Our findings are reported in the table.

MS-DRGs for Carotid Artery Stent Procedures			
MS-DRG	Number of Cases	Average Length of stay	Average Costs
034	1,259	6.9	$28,668
035	3,367	3.0	$17,114
036	4,769	1.4	$13,501

As shown in the table, we found a total of 1,259 cases in MS–DRG 034 with an average length of stay of 6.9 days and average costs of $28,668. We found a total of 3,367 cases in MS–DRG 035 with an average length of stay of 3.0 days and average costs of $17,114. We found a total of 4,769 cases in MS–DRG 036 with an average length of stay of 1.4 days and average costs of $13,501.

We then examined claims data from the September 2019 update of the FY 2019 MedPAR file for MS–DRGs 037, 038, and 039 and identified cases reporting any one of the 6 procedure codes listed in the table previously to determine the volume of cases impacted and if the average length of stay and average costs are consistent with the average length of stay and average costs for MS–DRGs 034, 035 and 036. Our finding are shown in the following table.

MS-DRGs for Extracranial Procedures				
MS-DRG	**ICD-10-PCS code**	**Number of Cases**	**Average Length of Stay**	**Average Costs**
037	All cases	3,331	7.3	$24,155
	Cases with procedure codes for dilation of a carotid artery with an intraluminal device using an open approach	6	7	$22,272
038	All cases	11,021	3.0	$12,306
	Cases with procedure codes for dilation of a carotid artery with an intraluminal device using an open approach	33	2.3	$16,777
039	All cases	20,854	1.4	$8,463
	Cases with procedure codes for dilation of a carotid artery with an intraluminal device using an open approach	26	1.2	$14,981

As shown in the table, we found a total of 3,331 cases with an average length of stay of 7.3 days and average costs of $24,155 in MS–DRG 037. There were 6 cases reporting at least one of the 6 procedure codes that describe dilation of the carotid artery with an intraluminal device using an open approach in MS–DRG 037 with an average length of stay of 7 days and average costs of $22,272. For MS–DRG 038, we found a total of 11,021 cases with an average length of stay of 3 days and average costs of $12,306. There were 33 cases reporting at least one of the 6 procedure codes that describe dilation of the carotid artery with an intraluminal device in MS–DRG 038 with an average length of stay of 2.3 days and average costs of $16,777. For MS–DRG 039, we found a total of 20,854 cases with an average length of stay of 1.4 days and average costs of $8,463. There were 26 cases reporting at least one of the 6 procedure codes that describe dilation of the carotid artery with an intraluminal device in MS–DRG 039 with an average length of stay of 1.2 days and average costs of $14,981.

The data analysis shows that for the cases in MS–DRGs 037, 038, and 039 reporting ICD–10–PCS codes 037H04Z, 037J04Z, 037K04Z, 037L04Z, 037M04Z, or 037N04Z, the average length of stay is shorter and the average costs are higher than the average length of stay and average costs (with the exception of the average costs for the 6 cases in MS–DRG 037 which are slightly less) in the FY 2019 MedPAR file for MS–DRGs 037, 038, and 039 respectively. The data analysis also shows for the cases in MS–DRGs 037, 038, and 039 reporting ICD–10–PCS codes 037H04Z, 037J04Z, 037K04Z, 037L04Z, 037M04Z, and 037N04Z the average length of stay and the average costs are in-line with the average length of stay and average costs in the FY 2019 MedPAR file for MS–DRGs 034, 035, and 036 respectively.

As noted in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19184) and final rule (84 FR 42077), our clinical advisors stated that MS–DRGs 034, 035 and 036 are defined to include only those procedure codes that describe procedures that involve dilation of a carotid artery with an intraluminal device.

Therefore, we are proposing to reassign the procedure codes listed in the table from MS–DRGs 037, 038, and 039 that describe procedures that involve dilation of the carotid artery with an intraluminal device to MS–DRGs 034, 035, and 036.

In addition to our analysis of the claims data from the September 2019 MedPAR file for MS–DRGs 037, 038, and 039, we conducted an examination of all the MS–DRGs where any one of the 6 procedure codes listed previously were also reported to determine if any one of the 6 procedure codes were included in any other MS–DRG outside of MDC 01, to further assess the current MS–DRG assignments. Our findings are shown in the following table.

Other MS-DRGs Reporting Procedures Codes 037H04Z, 037J04Z, 037K04Z, 037L04Z, 037M04Z, or 037N04Z			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
023	1	13	$79,797
027	1	1	$6,838
035	1	5	$14,300
219	1	5	$65,073
233	1	18	$59,259
235	1	45	$102,530
252	1	8	$36,020

As shown in the table, we found one case reporting any one of these 6 procedure codes in each of MS–DRGs 023, 027, 035, 219, 233, 235 and 252. We note that all of the listed MS–DRGs are assigned to MDC 01 with one exception: MS–DRG 252 (Other Vascular Procedures with MCC) in MDC05 (Diseases and Disorders of the Circulatory System). As a result, we reviewed the logic list for MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 05 and found 36 ICD–10–PCS codes for procedures that describe dilation of the carotid artery with an intraluminal device with an open approach that are not currently assigned in MDC 01. The 36 ICD–10–PCS codes are listed in the following table.

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Codes that Involve Dilation of a Carotid Artery with an Intraluminal Device in MDC 05 and not in MDC 01	
ICD-10-PCS Code	**Code Description**
037H05Z	Dilation of right common carotid artery with two drug-eluting intraluminal devices, open approach
037H06Z	Dilation of right common carotid artery with three drug-eluting intraluminal devices, open approach
037H07Z	Dilation of right common carotid artery with four or more drug-eluting intraluminal devices, open approach
037H0EZ	Dilation of right common carotid artery with two intraluminal devices, open approach
037H0FZ	Dilation of right common carotid artery with three intraluminal devices, open approach
037H0GZ	Dilation of right common carotid artery with four or more intraluminal devices, open approach
037J05Z	Dilation of left common carotid artery with two drug-eluting intraluminal devices, open approach
037J06Z	Dilation of left common carotid artery with three drug-eluting intraluminal devices, open approach
037J07Z	Dilation of left common carotid artery with four or more drug-eluting intraluminal devices, open approach
037J0EZ	Dilation of left common carotid artery with two intraluminal devices, open approach
037J0FZ	Dilation of left common carotid artery with three intraluminal devices, open approach
037J0GZ	Dilation of left common carotid artery with four or more intraluminal devices, open approach
037K05Z	Dilation of right internal carotid artery with two drug-eluting intraluminal devices, open approach
037K06Z	Dilation of right internal carotid artery with three drug-eluting intraluminal devices, open approach
037K07Z	Dilation of right internal carotid artery with four or more drug-eluting intraluminal devices, open approach
037K0EZ	Dilation of right internal carotid artery with two intraluminal devices, open approach
037K0FZ	Dilation of right internal carotid artery with three intraluminal devices, open approach
037K0GZ	Dilation of right internal carotid artery with four or more intraluminal devices, open approach
037L05Z	Dilation of left internal carotid artery with two drug-eluting intraluminal devices, open approach

037L06Z	Dilation of left internal carotid artery with three drug-eluting intraluminal devices, open approach
037L07Z	Dilation of left internal carotid artery with four or more drug-eluting intraluminal devices, open approach
037L0EZ	Dilation of left internal carotid artery with two intraluminal devices, open approach
037L0FZ	Dilation of left internal carotid artery with three intraluminal devices, open approach
037L0GZ	Dilation of left internal carotid artery with four or more intraluminal devices, open approach
037M05Z	Dilation of right external carotid artery with two drug-eluting intraluminal devices, open approach
037M06Z	Dilation of right external carotid artery with three drug-eluting intraluminal devices, open approach
037M07Z	Dilation of right external carotid artery with four or more drug-eluting intraluminal devices, open approach
037M0EZ	Dilation of right external carotid artery with two intraluminal devices, open approach
037M0FZ	Dilation of right external carotid artery with three intraluminal devices, open approach
037M0GZ	Dilation of right external carotid artery with four or more intraluminal devices, open approach
037N05Z	Dilation of left external carotid artery with two drug-eluting intraluminal devices, open approach
037N06Z	Dilation of left external carotid artery with three drug-eluting intraluminal devices, open approach
037N07Z	Dilation of left external carotid artery with four or more drug-eluting intraluminal devices, open approach
037N0EZ	Dilation of left external carotid artery with two intraluminal devices, open approach
037N0FZ	Dilation of left external carotid artery with three intraluminal devices, open approach
037N0GZ	Dilation of left external carotid artery with four or more intraluminal devices, open approach

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We then examined the claims data to determine if there were other MS–DRGs in which one of the 36 procedure codes listed in the table were reported. We found 8 cases that grouped to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) when a principal diagnosis from MDC 01 was reported with one of the procedure codes in the table that describes dilation of a carotid artery with an intraluminal device, open approach.

As noted previously, in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19184) and final rule (84 FR 42077), our clinical advisors stated that MS–DRGs 034, 035, and 036 are defined to include those procedure codes that describe procedures that involve dilation of a carotid artery with an intraluminal device. Our clinical advisors support adding the 36 ICD–10–PCS codes identified in the table to MS–DRGs 034, 035, and 036 in MDC 01 for consistency to align with the definition of MS–DRGs 034, 035, and 036 and also to permit proper case assignment when a principal diagnosis from MDC 01 is reported with one of the procedure codes in the table that describes dilation of a carotid artery with an intraluminal device, open approach.

Therefore, for FY 2021, we are also proposing to add the 36 ICD–10–PCS codes identified in the table that are currently assigned in MDC 05 to MS–DRGs 252, 253, and 254 to the GROUPER logic for MS–DRGs 034, 035, and 036 in MDC 01.

b. Epilepsy with Neurostimulator

We received a request to reassign cases describing the insertion of a neurostimulator generator into the skull in combination with the insertion of a neurostimulator lead into the brain from MS–DRG 023 (Craniotomy with Major Device Implant or Acute Complex Central Nervous System (CNS) Principal Diagnosis (PDX) with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator) to MS–DRG 021 (Intracranial Vascular Procedures with PDX Hemorrhage with CC) or to reassign

these cases to another MS–DRG for more appropriate payment. The Responsive Neurostimulator (RNS©) System, a cranially implanted neurostimulator that is a treatment option for persons diagnosed with medically intractable epilepsy, is identified by the reporting of an ICD–10–PCS code combination capturing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain and cases are assigned to MS–DRG 023 when reported with a principal diagnosis of epilepsy.

As discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38015 through 38019), we finalized our proposal to reassign all cases with a principal diagnosis of epilepsy and one of the following ICD–10–PCS code combinations capturing cases with a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator) to MS–DRG 023 even if there is no MCC reported:

- 0NH00NZ (Insertion of neurostimulator generator into skull, open approach), in combination with 00H00MZ (Insertion of neurostimulator lead into brain, open approach).
- 0NH00NZ (Insertion of neurostimulator generator into skull, open approach), in combination with 00H03MZ (Insertion of neurostimulator lead into brain, percutaneous approach).
- 0NH00NZ (Insertion of neurostimulator generator into skull, open approach), in combination with 00H04MZ (Insertion of neurostimulator lead into brain, percutaneous endoscopic approach).

We also finalized our proposed change to the title of MS–DRG 023 from ''Craniotomy with Major Device Implant or Acute Complex Central Nervous System (CNS) Principal Diagnosis (PDX) with MCC or Chemo Implant'' to ''Craniotomy with Major Device Implant or Acute Complex Central Nervous System (CNS) Principal Diagnosis (PDX) with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator'' to reflect the modifications to the MS–DRG structure.

The requestor acknowledged the refinements made to MS–DRG 023 effective for FY 2018, but stated that despite the previously-mentioned changes, cases describing the insertion of a neurostimulator generator into the skull in combination with the insertion of a neurostimulator lead into the brain continue to be underpaid. The requestor performed its own analysis and stated that it found that the average costs of cases describing the insertion of the RNS© neurostimulator were significantly higher than the average costs of all cases in their current assignment to MS–DRG 023, and as a result, cases describing the insertion of the RNS© neurostimulator are not being adequately reimbursed. The requestor suggested the following two options for MS–DRG assignment updates: (1) Reassign cases describing the insertion of a neurostimulator generator into the skull in combination with the insertion of a neurostimulator lead into the brain from MS–DRG 023 to MS–DRG 021 with a change in title to ''lntracranial Vascular Procedures with PDX Hemorrhage with CC or Epilepsy with Neurostimulator;'' or (2) reassign cases describing the insertion of a neurostimulator generator into the skull in combination with the insertion of a neurostimulator lead into the brain to another higher paying MS–DRG that would provide adequate reimbursement. The requestor stated its belief that MS–DRG 021 is a better fit in terms of average costs and clinical coherence for reassignment of RNS© System cases and recognized that there is likely still not enough volume to warrant the creation of new MS–DRGs for cases describing the insertion of the RNS© neurostimulator.

We examined claims data from the September 2019 update of the FY 2019 MedPAR file for all cases in MS–DRG 023 and compared the results to cases representing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator) that had a principal diagnosis of epilepsy in MS–DRG 023. The following table shows our findings:

MS-DRG 023	Number of Cases	Average Length of Stay	Average Costs
All cases	11,938	9.8	$40,264
Cases with principal diagnosis of epilepsy with neurostimulator generator inserted into the skull and insertion of a neurostimulator lead into brain	81	3.3	$52,362

As shown in the table, for MS–DRG 023, we identified a total of 11,938 cases, with an average length of stay of 9.8 days and average costs of $40,264. Of the 11,938 cases in MS–DRG 023, there were 81 cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator) that had a principal diagnosis of epilepsy with an average length of stay of 3.3 days and average costs of $52,362. Our clinical advisors reviewed these data, and agreed with the requestor that the number of cases is too small to warrant the creation of a new MS–DRG for these cases, for the reasons discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38015 through 38019).

We also examined the reassignment of cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator) to MS–DRGs 020, 021, and 022 (Intracranial Vascular Procedures with PDX Hemorrhage with MCC, with CC, and without CC/MCC, respectively). While the request was to reassign these cases to MS–DRG 021, MS–DRG 021 is specifically differentiated according to the presence of a secondary diagnosis with a severity level designation of a complication or comorbidity (CC). Cases with a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator) do not always involve the presence of a secondary diagnosis with a severity level designation of a complication or comorbidity (CC), and therefore we reviewed data for all three MS–DRGs. The following table shows our findings:

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
020	1,623	16.1	$75,668
021	409	12.3	$55,123
022	131	6.3	$35,599

As shown in the table, for MS–DRG 020, there were a total of 1,623 cases with an average length of stay of 16.1 days and average costs of $75,668. For MS–DRG 021, there were a total of 409 cases with an average length of stay of 12.3 days and average costs of $55,123. For MS–DRG 022, there were a total of 131 cases with an average length of stay of 6.3 days and average costs of $35,599.

While the cases in MS–DRG 023 describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator) and a principal diagnosis of epilepsy have average costs that are similar to the average costs of cases in MS–DRG 021 ($52,362 compared to $55,123), they have an average length of stay that is 9 days shorter (3.3 days compared to 12.3 days), similar to our findings as summarized in the FY 2018 IPPS/LTCH PPS final rule. Our clinical advisors reviewed the clinical issues and the claims data, and did not support reassigning the cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator) and a principal diagnosis of epilepsy from MS–DRG 023 to MS–DRGs 020, 021 or 022. As discussed in the FY 2018 IPPS/LTCH PPS final rule, the cases in MS–DRGs 020, 021 and 022 have a principal diagnosis of a hemorrhage. The RNS© neurostimulator generators are not used to treat patients with diagnosis of a hemorrhage. Our clinical advisors continue to believe that it is inappropriate to reassign cases representing a principal diagnosis of epilepsy to a MS–DRG that contains cases that represent the treatment of intracranial hemorrhage, as discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38015 through 38019). They also stated that the differences in average length of stay and average costs based on the more recent data continue to support this recommendation.

We then explored alternative options, as was requested. We noted that the 81 cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator) and a principal diagnosis of epilepsy had an average length of stay of 3.3 days and average costs of $52,362, as compared to the 11,938 cases in MS–DRG 023 that had an average length of stay of 9.8 days and average costs of $40,264. While these neurostimulator cases had average costs that were $12,098 higher than the average costs of all cases in MS–DRG 023, there were only a total of 81 cases. There may have been other factors contributing to the higher costs.

We further analyzed the data to identify those cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator), with at least one other procedure designated as an O.R. procedure, and a principal diagnosis of epilepsy. This approach can be useful in determining whether resource use is truly associated with a particular procedure or whether the procedure frequently occurs in cases with other procedures with higher than average resource use. Our data findings for MS–DRG 023 demonstrate that of the 81 cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator) and a principal diagnosis of epilepsy, 19 reported at least one other procedure designated as an O.R. procedure, and had higher average costs ($72,995 versus $52,362) compared to the average costs of all cases in this subset of MS–DRG 023.

We also reviewed the cases reporting procedures describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator), and a principal diagnosis of epilepsy to identify the secondary diagnosis CC and/or MCC conditions reported in conjunction with these procedures that also may be contributing to the higher average costs for these cases. We reviewed the claims data to identify the number (frequency) and types of principal and secondary diagnosis CC and/or MCC conditions that were reported. Our findings for the cases reporting secondary diagnosis MCC and CC conditions, followed by the top 10 secondary diagnosis MCC and secondary diagnosis CC conditions that were reported within the claims data for this subset of cases are shown in the following tables:

MS-DRG 023: Principal diagnosis of epilepsy with neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into brain	Number of Cases	Average Length of Stay	Average Costs
With MCC	12	9.1	$69,213
With CC	44	6.9	$62,265

Top 10 Secondary Diagnosis MCC Conditions Reported with Procedure Code with a Neurostimulator Generator Inserted Into The Skull With The Insertion Of a Neurostimulator Lead Into The Brain and a Principal Diagnosis of Epilepsy				
ICD-10-CM Code	**Description**	**Number of Times Reported**	**Average Length of Stay**	**Average Costs**
G93.41	Metabolic encephalopathy	2	13	$89,413
G93.5	Compression of brain	2	15	$102,406
G93.6	Cerebral edema	2	9.5	$81,441
G80.0	Spastic quadriplegic cerebral palsy	1	2	$78,488
I62.1	Nontraumatic extradural hemorrhage	1	8	$25,946
I63.432	Cerebral infarction due to embolism of left posterior cerebral artery	1	2	$41,277
J69.0	Pneumonitis due to inhalation of food and vomit	1	10	$54,241
J96.00	Acute respiratory failure, unspecified whether with hypoxia or hypercapnia	1	2	$29,846
J96.01	Acute respiratory failure with hypoxia	1	10	$54,241

Top 10 Secondary Diagnosis CC Conditions Reported with Procedure Code with a Neurostimulator Generator Inserted Into The Skull With The Insertion Of a Neurostimulator Lead Into The Brain and a Principal Diagnosis of Epilepsy				
ICD-10-CM Code	**Description**	**Number of Times Reported**	**Average Length of Stay**	**Average Costs**
E87.1	Hypo-osmolality and hyponatremia	5	3.4	$41,375
R47.01	Aphasia	4	6.8	$110,672
Z68.41	Body mass index (BMI) 40.0-44.9, adult	3	3.7	$39,620
F84.0	Autistic disorder	2	13.5	$47,357
G81.91	Hemiplegia, unspecified affecting right dominant side	2	15	$102,406
G97.61	Postprocedural hematoma of a nervous system organ or structure following a nervous system procedure	2	13	$89,413
R45.851	Suicidal ideations	2	8	$35,561
D68.9	Coagulation defect, unspecified	1	1	$39,700
D69.3	Immune thrombocytopenic purpura	1	1	$39,961
E22.2	Syndrome of inappropriate secretion of antidiuretic hormone	1	4	$12,705

While the results of the claims analysis as previously summarized indicate that the average costs of cases reporting a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator), and a principal diagnosis of epilepsy are higher compared to the average costs for all cases in their assigned MS–DRG, we cannot ascertain from the claims data the resource use specifically attributable to the procedure during a hospital stay. These data show cases reporting a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator), and a principal diagnosis of epilepsy, can present greater treatment difficulty, and have a need for additional intervention with other O.R. procedures. When reviewing consumption of hospital resources for this subset of cases, the claims data also clearly shows that the patients typically have multiple MCC and CC conditions, and the increased costs appear to be attributable to the severity of illness of the patient.

In summary, we believe that further analysis of cases reporting a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator), and a principal diagnosis of epilepsy is needed prior to proposing any further reassignment of these cases to ensure clinical coherence between these cases and the other cases with which they may potentially be grouped. We expect that, in future years, we would have additional data that exhibit an increased number of cases that could be used to evaluate the potential reassignment of cases reporting a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator), and a principal diagnosis of epilepsy. Therefore, we are not proposing to reassign cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator) from MS–DRG 023 to MS–DRG 021. We are also not proposing to reassign Responsive Neurostimulator (RNS©) System cases to another MS–DRG at this time.

4. MDC 3 (Diseases and Disorders of Ear, Nose and Throat): Temporomandibular Joint Replacements

We received a request to consider reassignment of ICD–10–PCS procedure codes 0RRC0JZ (Replacement of right temporomandibular joint with synthetic substitute, open approach) and 0RRD0JZ (Replacement of left temporomandibular joint with synthetic substitute, open approach) from MS–DRGs 133 and 134 (Other Ear, Nose, Mouth and Throat O.R. Procedures with and without CC/MCC, respectively) to MS–DRGs 131 and 132 (Cranial and Facial Procedures with and without CC/MCC, respectively) in MDC 03.

The requestor stated that it is inaccurate for procedure codes 0RRC0JZ and 0RRD0JZ that identify and describe replacement of the temporomandibular joint (TMJ), which involves excision of the TMJ followed by replacement with a prosthesis, to group to MS–DRGs 133 and 134 while excision of the TMJ alone, identified by procedure codes 0RBC0ZZ (Excision of right temporomandibular joint, open approach) and 0RBD0ZZ (Excision of left temporomandibular joint, open

approach), groups to the higher weighted MS–DRGs 131 and 132. According to the requestor, reassignment of procedure codes 0RRC0JZ and 0RRD0JZ to the higher weighted MS–DRGs 131 and 132 is reasonable and the MS–DRG title of ''Cranial and Facial Procedures'' is more appropriate. However, the requestor also stated that the cost of the prosthesis would continue to be underpaid, despite that recommended reassignment. As an alternative option, the requestor suggested CMS analyze if there may be other higher weighted MS–DRGs that could more appropriately compensate providers for a TMJ replacement with prosthesis procedure.

In addition, the requestor recommended that we analyze all procedures involving the mandible and maxilla and consider reassignment of those procedure codes from MS–DRGs 129 (Major Head and Neck Procedures with CC/MCC or Major Device) and 130 (Major Head and Neck Procedures without CC/MCC) to MS–DRGs 131 and 132 because the codes describe procedures that are performed on facial and cranial structures. Finally, the requestor also suggested another option that included modifying the surgical hierarchy for MDC 03 by sequencing MS–DRGs 131 and 132 above MS–DRGs 129 and 130, which the requestor asserted would provide for more appropriate payment to providers for the performance of multiple facial procedures.

In this section of this proposed rule, we discuss these separate but related requests that involve procedures currently assigned to MS–DRGs 129, 130, 131, 132, 133 and 134 in MDC 03.

To analyze the request involving temporomandibular joint replacements, we first identified the ICD–10–PCS procedure codes that describe the excision or replacement of a temporomandibular joint as shown in the following table.

ICD-10-PCS Code	Description
0RBC0ZZ	Excision of right temporomandibular joint, open approach
0RBC3ZZ	Excision of right temporomandibular joint, percutaneous approach
0RBC4ZZ	Excision of right temporomandibular joint, percutaneous endoscopic approach
0RBD0ZZ	Excision of left temporomandibular joint, open approach
0RBD3ZZ	Excision of left temporomandibular joint, percutaneous approach
0RBD4ZZ	Excision of left temporomandibular joint, percutaneous endoscopic approach
0RRC07Z	Replacement of right temporomandibular joint with autologous tissue substitute, open approach
0RRC0JZ	Replacement of right temporomandibular joint with synthetic substitute, open approach
0RRC0KZ	Replacement of right temporomandibular joint with nonautologous tissue substitute, open approach
0RRD07Z	Replacement of left temporomandibular joint with autologous tissue substitute, open approach
0RRD0JZ	Replacement of left temporomandibular joint with synthetic substitute, open approach
0RRD0KZ	Replacement of left temporomandibular joint with nonautologous tissue substitute, open approach

The requestor is correct that procedure codes 0RRC0JZ and 0RRD0JZ that describe replacement of the right and left TMJ with a prosthesis (synthetic substitute) by an open approach group to MS–DRGs 133 and 134 and procedure codes 0RBC0ZZ and 0RBD0ZZ that describe excision of the right and left TMJ alone by an open approach group to the higher weighted MS–DRGs 131 and 132. We also note that the corresponding related codes as previously listed in the table that describe different approaches (excision procedures) or different types of tissue substitute (replacement procedures) are also assigned to the same respective MS–DRGs.

We examined claims data from the September 2019 update of the FY 2019 MedPAR file for MS–DRGs 133 and 134 to identify cases reporting ICD–10–PCS codes 0RRC0JZ or 0RRD0JZ. Our findings are shown in the following table.

MS-DRG	ICD-10-PCS Code	Number of Cases	Average Length of Stay	Average Costs
133	All Cases	1,757	5.6	$15,337
	0RRC0JZ or 0RRD0JZ	13	3.1	$21,677
134	All Cases	849	2.5	$9,512
	0RRC0JZ or 0RRD0JZ	23	2.1	$20,430

In MS–DRG 133, we found a total of 1,757 cases with an average length of stay of 5.6 days and average costs of $15,337. Of those 1,757 cases, there were 13 cases reporting ICD–10–PCS code 0RRC0JZ or 0RRD0JZ, with an average length of stay of 3.1 days and average costs of $21,677. In MS–DRG 134, we found a total of 849 cases with an average length of stay of 2.5 days and average costs of $9,512. Of those 849 cases, there were 23 cases reporting ICD–10–PCS code 0RRC0JZ or 0RRD0JZ, with an average length of stay of 2.1 days and average costs of $20,430. The analysis shows that cases reporting ICD–10–PCS procedure codes 0RRC0JZ or 0RRD0JZ in MS–DRGs 133 and 134 have higher average costs ($21,677 versus $15,337 and $20,430 versus $9,512, respectively) and shorter lengths of stay (3.1 days versus 5.6 days and 2.1 days versus 2.5 days, respectively) compared to all the cases in their assigned MS–DRG.

We also examined claims data from the September 2019 update of the FY 2019 MedPAR file for MS–DRGs 131 and 132. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
131	1,181	5.4	$18,875
132	464	2.5	$11,558

In MS–DRG 131, we found a total of 1,181 cases with an average length of stay of 5.4 days and average costs of $18,875. In MS–DRG 132, we found a total of 464 cases with an average length of stay of 2.5 days and average costs of $11,558.

Overall, the data analysis shows that the average costs for the cases reporting procedure codes 0RRC0JZ and 0RRD0JZ in MS–DRGs 133 and 134 are more aligned with the average costs for all the cases in MS–DRG 131 ($21,677 and $20,430, respectively versus $18,875) compared to MS–DRG 132 where the average costs are not significantly different than the average costs of all the cases in MS–DRG 134 ($11,558 versus $9,512). Our clinical advisors agreed that the replacement of a TMJ with prosthesis procedures (codes 0RRC0JZ or 0RRD0JZ) are more resource intensive and are clinically distinct from the cases reporting procedure codes 0RBC0ZZ and 0RBD0ZZ that involve excision of the TMJ alone. They also agreed that procedure codes 0RRC0JZ and 0RRD0JZ should be reassigned to a higher weighted MS–DRG. However, they recommended we conduct further claims analysis to identify if there are other MS–DRGs in MDC 03 where cases reporting these procedure codes may also be found and to compare that data.

As previously noted, the requestor had also recommended that we analyze all procedures involving the mandible and maxilla and consider reassignment of those procedure codes from MS–DRGs 129 and 130 to MS–DRGs 131 and 132. The requestor did not provide a specific list of the procedure codes involving the mandible and maxilla, therefore, we reviewed the list of procedure codes in MS–DRGs 129 and 130 and identified the following 26 procedure codes describing procedures performed on the mandible. There were no procedure codes describing procedures performed on the maxilla in MS–DRGs 129 and 130.

0NBT0ZZ	Excision of right mandible, open approach
0NBT3ZZ	Excision of right mandible, percutaneous approach
0NBT4ZZ	Excision of right mandible, percutaneous endoscopic approach
0NBV0ZZ	Excision of left mandible, open approach
0NBV3ZZ	Excision of left mandible, percutaneous approach
0NBV4ZZ	Excision of left mandible, percutaneous endoscopic approach
0NRT07Z	Replacement of right mandible with autologous tissue substitute, open approach
0NRT0JZ	Replacement of right mandible with synthetic substitute, open approach
0NRT0KZ	Replacement of right mandible with nonautologous tissue substitute, open approach
0NRT37Z	Replacement of right mandible with autologous tissue substitute, percutaneous approach
0NRT3JZ	Replacement of right mandible with synthetic substitute, percutaneous approach
0NRT3KZ	Replacement of right mandible with nonautologous tissue substitute, percutaneous approach
0NRT47Z	Replacement of right mandible with autologous tissue substitute, percutaneous endoscopic approach
0NRT4JZ	Replacement of right mandible with synthetic substitute, percutaneous endoscopic approach
0NRT4KZ	Replacement of right mandible with nonautologous tissue substitute, percutaneous endoscopic approach
0NRV07Z	Replacement of left mandible with autologous tissue substitute, open approach
0NRV0JZ	Replacement of left mandible with synthetic substitute, open approach
0NRV0KZ	Replacement of left mandible with nonautologous tissue substitute, open approach
0NRV37Z	Replacement of left mandible with autologous tissue substitute, percutaneous approach
0NRV3JZ	Replacement of left mandible with synthetic substitute, percutaneous approach
0NRV3KZ	Replacement of left mandible with nonautologous tissue substitute, percutaneous approach
0NRV47Z	Replacement of left mandible with autologous tissue substitute, percutaneous endoscopic approach
0NRV4JZ	Replacement of left mandible with synthetic substitute, percutaneous endoscopic approach
0NRV4KZ	Replacement of left mandible with nonautologous tissue substitute, percutaneous endoscopic approach
0NTT0ZZ	Resection of right mandible, open approach
0NTV0ZZ	Resection of left mandible, open approach

Based on the advice of our clinical advisors as previously discussed, we conducted additional analyses for MDC 03 using the same FY 2019 MedPAR data file and found cases reporting procedure code 0RRC0JZ or 0RRD0JZ for the replacement of a TMJ with prosthesis procedure in MS–DRGs 129, 130, 131, and 132. As discussed in section II.D.15. of this proposed rule, cases with multiple procedures are assigned to the highest surgical class in the hierarchy to which one of the procedures is assigned. For example, if procedure code 0RRC0JZ which is assigned to the logic for MS–DRGs 133 and 134 is reported on a claim with procedure code 0NSR04Z (Reposition maxilla with internal fixation device, open approach), which is assigned to the logic for MS–DRGs 131 and 132, the case will group to MS–DRG 131 or 132 (depending on the presence of a CC or MCC) when reported with a principal diagnosis from MDC 03 because MS–DRGs 131 and 132 are sequenced higher in the surgical hierarchy than MS–DRGs 133 and 134. Therefore, since MS–DRGs 129, 130, 131, and 132 are sequenced higher in the surgical hierarchy than MS–DRGs 133 and 134 in MDC 03, cases reporting procedure code 0RRC0JZ or 0RRD0JZ along with another O.R. procedure that is currently assigned to one of those MS–DRGs in the GROUPER logic results in case assignment to one of those higher surgical class MS–DRGs. We also identified cases reporting procedures performed on the mandible from the previously discussed list of procedure codes in MS–DRGs 129 and 130. Our findings are shown in the following table.

MS-DRG	ICD-10-PCS Code	Number of Cases	Average Length of Stay	Average Costs
129	All Cases	2,080	5.2	$18,091
	0RRC0JZ or 0RRD0JZ	3	3	$33,581
	Mandible Procedure	592	6.9	$21,258
130	All Cases	948	2.7	$11,092
	0RRC0JZ or 0RRD0JZ	5	3.4	$27,396
	Mandible Procedure	202	3.5	$14,712
131	All Cases	1,181	5.4	$18,875
	0RRC0JZ or 0RRD0JZ	4	7.3	$31,151
132	All Cases	464	2.5	$11,558
	0RRC0JZ or 0RRD0JZ	10	3.1	$24,099

As shown in the table, for MS–DRG 129, there was a total of 2,080 cases with average length of stay of 5.2 days and average costs of $18,091. Of these 2,080 cases, there were 3 cases reporting a TMJ replacement with prosthesis procedure (code 0RRC0JZ or 0RRD0JZ) with an average length of stay of 3 days and average costs of $33,581 and 592 cases reporting a mandible procedure with average length of stay of 6.9 days and average costs of $21,258. For MS–DRG 130, there was a total of 948 cases with average length of stay of 2.7 days and average costs of $11,092. Of these 948 cases, there were 5 cases reporting a TMJ replacement with prosthesis procedure (code 0RRC0JZ or 0RRD0JZ) with an average length of stay of 3.4 days and average costs of $27,396 and 202 cases reporting a mandible procedure with average length of stay of 3.5 days and average costs of $14,712. For MS–DRG 131, there was a total of 1,181 cases with average length of stay of 5.4 days and average costs of $18,875. Of these 1,181 cases there were 4 cases reporting a TMJ replacement with prosthesis procedure (code 0RRC0JZ or 0RRD0JZ) with an average length of stay of 7.3 days and average costs of $31,151. For MS–DRG 132, there was a total of 464 cases with average length of stay of 2.5 days and average costs of $11,558. Of these 464 cases, there were 10 cases reporting a TMJ replacement with prosthesis procedure (code 0RRC0JZ or 0RRD0JZ) with an average length of stay of 3.1 days and average costs of $24,099.

The data analysis demonstrates that the average costs of cases reporting procedure code 0RRC0JZ or 0RRD0JZ for the replacement of a TMJ with prosthesis procedure in MS–DRGs 129, 130, 131, and 132 and the cases reporting procedures performed on the mandible in MS–DRGs 129 and 130 have higher average costs compared to all the cases in their assigned MS–DRGs. While the volume of the cases reporting procedure code 0RRC0JZ or 0RRD0JZ was low with a total of 22 cases across MS–DRGs 129, 130, 131, and 132, similar to the analysis results for MS–DRGs 133 and 134 described earlier, the average costs for the cases are higher ($33,581 versus $18,091; $27,396 versus $11,092; $31,151 versus $18,875; and $24,099 versus $11,558) affirming that replacement of a TMJ with prosthesis procedures are more costly. The analysis also demonstrates that the average length of stay for cases reporting procedure code 0RRC0JZ or 0RRD0JZ across MS–DRGs 130, 131, and 132 is longer (3.4 days versus 2.7 days; 7.3 days versus 5.4 days; and 3.1 days versus 2.5 days) compared to all the cases in their assigned MS–DRGs. For MS–DRG 129, we found that the average length of stay was shorter (3 days versus 5.2 days) for cases reporting procedure code 0RRC0JZ or 0RRD0JZ. The data demonstrated similar results for the cases reporting procedures performed on the mandible in MS–DRGs 129 and 130, where the average costs for the cases are higher ($21,258 versus $18,091 and $14,712 versus $11,092, respectively) and the average length of stay was longer (6.9 days versus 5.2 days and 3.5 days versus 2.7 days, respectively) compared to all the cases in their assigned MS–DRG.

The analysis of MS–DRGs 129, 130, 131, and 132 further demonstrated that the average length of stay and average costs for all cases were almost identical for each of the subgroups. For example, MS–DRG 129 is defined as ''with CC/MCC or major device'' and MS–DRG 131 is defined as ''with CC/MCC'' while MS–DRGs 130 and 132 are both defined as ''without CC/MCC''. For all of the cases in MS–DRG 129, we found that the average length of stay was 5.2 days with an average cost of $18,091, and for all of the cases in MS–DRG 131, the average length of stay was 5.4 days with an average cost of $18,875. Similarly, for all of the cases in MS–DRG 130, we found that the average length of stay was 2.7 days with an average cost of $11,092, and for MS–DRG 132, we found the average length of stay was 2.5 days with an average cost of $11,558.

As a result of the data analysis performed for MS–DRGs 129, 130, 131, and 132, including the analysis of the procedures describing replacement of a TMJ with prosthesis in MS–DRGs 133 and 134, as well as considering the requestor's suggestion that we examine the appropriateness of modifying the surgical hierarchy for MDC 03 by sequencing MS–DRGs 131 and 132 above MS–DRGs 129 and 130 to enable more appropriate payment for the performance of multiple facial procedures, our clinical advisors recommended evaluating all the procedures currently assigned to MS–DRGs 129, 130, 131, 132, 133, and 134 to compare costs, complexity of service and clinical coherence to assess any potential reassignment of these procedures. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 37, which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*, for complete documentation of the GROUPER logic for MS–DRGs 129, 130, 131, 132, 133, and 134.

We examined claims data from the September 2019 update of the FY 2019 MedPAR file for cases reporting any of the procedure codes that are currently assigned to MS–DRGs 129, 130, 131, 132, 133, or 134. We refer the reader to Table 6P.2d associated with this proposed rule (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index/* for the detailed analysis. We note that if a procedure code that is currently assigned to MS–DRGs 129, 130, 131, 132, 133, or 134 is not displayed it is because there were no cases found reporting that code in the assigned MS–DRG.

The data analysis shows that there is wide variation in the volume, length of stay, and average costs of cases reporting procedures currently assigned to MS–DRGs 129, 130, 131, 132, 133, and 134. There were several instances in which only one case was found to report a procedure code from MS–DRG 129, 130, 131, 132, 133, or 134, and the average length of stay for these specific cases ranged from 1 day to 31 days. For example, in MS–DRG 131, we found one case reporting procedure code 0NB70ZZ (Excision of occipital bone, open approach) with an average length of stay of 31 days which we consider to be an outlier in comparison to all the other cases reported in that MS–DRG with an average length of stay of 5.4 days. Overall, the average costs of cases in MS–DRGs 129 and 130 range from $4,970 to $38,217, the average costs of cases in MS–DRGs 131 and 132 range from $4,022 to $69,558 and the average costs of cases in MS–DRGs 133 and 134 range from $1,089 to $87,569. As noted previously, the data demonstrate there appear to be similar utilization of hospital resources specifically for cases reported in MS–DRGs 129, 130, 131 and 132.

The highest volume of cases was reported in MS–DRGs 129 and 130 for the procedure codes describing resection of the right and left neck lymphatic. For MS–DRG 129, there was a total of 750 cases reporting procedure code 07T10ZZ (Resection of right neck lymphatic, open approach) with an average length of stay of 4.7 days and average costs of $17,155 and there was a total of 679 cases reporting procedure code 07T20ZZ (Resection of left neck lymphatic, open approach) with an average length of stay of 4.8 days and average costs of $17,857. For MS–DRG 130, there was a total of 358 cases reporting procedure code 07T10ZZ with an average length of stay of 2.6 days and average costs of $10,432 and there was

a total of 331 cases reporting procedure code 07T20ZZ with an average length of stay of 2.5 days and average costs of $10,467. For MS–DRGs 131 and 132, the highest volume of cases was reported for the procedure codes describing repositioning of the maxilla with internal fixation and repositioning of the right and left mandible with internal fixation. For MS–DRG 131, there was a total of 186 cases reporting procedure code 0NSR04Z (Reposition maxilla with internal fixation device, open approach) with an average length of stay of 5.1 days and average costs of $20,500; a total of 114 cases reporting procedure code 0NST04Z (Reposition right mandible with internal fixation device, open approach) with an average length of stay of 5.7 days and average costs of $18,710, and a total of 219 cases reporting procedure code 0NSV04Z (Reposition left mandible with internal fixation device, open approach) with an average length of stay of 6.0 days and average costs of $20,202. For MS–DRG 132, there was a total of 84 cases reporting procedure code 0NSR04Z with an average length of stay of 2.1 days and average costs of $12,991 and a total of 101 cases reporting procedure code 0NSV04Z with an average length of stay of 2.8 days and average costs of $11,386. For MS–DRGs 133 and 134, the highest volume of cases was reported for the procedure codes describing excision of the facial nerve or nasal turbinate. For MS–DRG 133, there was a total of 60 cases reporting procedure code 09BL8ZZ (Excision of nasal turbinate, via natural or artificial opening endoscopic) with an average length of stay of 6.6 days and average costs of $21,253 and for MS–DRG 134, there was a total of 50 cases reporting procedure code 00BM0ZZ (Excision of facial nerve, open approach) with an average length of stay of 1.4 days and average costs of $8,048.

Our clinical advisors reviewed the procedures currently assigned to MS–DRGs 129, 130, 131, 132, 133, and 134 to identify the patient attributes that currently define each of these procedures and to group them with respect to complexity of service and resource intensity. For example, procedures that we believe represent greater treatment difficulty and reflect a class of patients who are similar clinically with regard to consumption of hospital resources were grouped separately from procedures that we believe to be less complex but still reflect patients who are similar clinically with regard to consumption of hospital resources. This approach differentiated the more complex and invasive procedures, such as resection of cervical lymph nodes, repositioning of facial bones, and excision of mandible procedures from the less complex and less invasive procedures such as excisions (biopsies) of lymph nodes and facial nerves, drainage procedures of the upper respiratory system, and tonsillectomies.

After this comprehensive review of all the procedures currently assigned to MS–DRGs 129, 130, 131, 132, 133, and 134, in combination with the results of the data analysis discussed previously, our clinical advisors support distinguishing the procedures currently assigned to those MS–DRGs by clinical intensity, complexity of service and resource utilization and also support restructuring of these MS–DRGs accordingly. We note that during the analysis of the procedures currently assigned to MS–DRGs 129 and 130, we recognized the special logic defined as ''Major Device Implant'' for MS–DRG 129 that identifies procedures describing the insertion of a cochlear implant or other hearing device. Our clinical advisors supported the removal of this special logic from the definition for assignment to any proposed modifications to the MS–DRGs, noting the costs of the device have stabilized over time and the procedures can be appropriately grouped along with other procedures involving devices in any restructured proposed MS–DRGs. We also identified 2 procedure codes currently assigned to MS–DRGs 131 and 132, 00J00ZZ (Inspection of brain, open approach) and 0WJ10ZZ (Inspection of cranial cavity, open approach), that our clinical advisors agreed should not be included in any proposed modifications to the MS–DRGs in MDC 03, stating that they are appropriately assigned to MS–DRGs in MDC 01 (Diseases and Disorders of the Nervous System). We further note that during our analysis of the procedures currently assigned to MS–DRGs 133 and 134, we found 338 procedure codes that were inadvertently included as a result of replication during our transition from the ICD–9 to ICD–10 based MS–DRGs. We refer the reader to Table 6P.2c for a detailed list of these procedure codes that describe procedures performed on various sites, such as the esophagus, stomach, intestine, skin, and thumb that, our clinical advisors agree should be removed from the definition for assignment to any proposed modifications to the MS–DRGs under MDC 03.

As a result of our review, we are proposing the deletion of MS–DRGs 129, 130, 131, 132, 133, and 134, and the creation of six new MS–DRGs. Currently, MS–DRGs 129, 131, and 133 are defined as base MS–DRGs, each of which is split by a two-way severity level subgroup. Our proposal includes the creation of two new base MS–DRGs with a three-way severity level split. Our clinical advisors suggested that based on the analysis of procedures currently assigned to MS–DRGs 129, 130, 131, 132, 133, and 134 as described previously, only 2 base MS–DRGs were needed, each divided into 3 levels according to the presence of a CC or MCC. The proposed MS–DRGs were developed consistent with the analysis to differentiate the more complex and invasive procedures from the less complex and less invasive procedures. As noted previously, our analysis of MS–DRGs 129, 130, 131, and 132 demonstrated that the average length of stay and average costs for all cases were almost identical for each of the severity level subgroups and therefore, the procedures assigned to these MS–DRGs were initially reviewed together as one clinical group and then evaluated further in comparison to the procedures currently assigned to MS–DRGs 133 and 134. The objective was to better differentiate procedures by treatment difficulty, clinical similarity, and resource use, and to propose a more appropriate restructuring. For example, based on this analysis, in some instances, we are proposing to reassign procedures described by procedure codes that are currently assigned to MS–DRGs 129 and 130 or MS–DRGs 131 and 132 to what is being defined as the less complex MS–DRGs. We believe the resulting proposed MS–DRG assignments are more clinically homogeneous, coherent and better reflect hospital resource use.

We applied the criteria to create subgroups for the three-way severity level split for the proposed new MS–DRGs and found that all five criteria were met. For the proposed new MS–DRGs, there is at least (1) 500 cases in the MCC group, the CC group and the NonCC group; (2) 5 percent of the cases in the MCC group, the CC group and the NonCC group; (3) a 20 percent difference in average costs between the MCC group, the CC group and the NonCC group; (4) a $2,000 difference in average costs between the MCC group, the CC group and the NonCC group; and (5) a 3-percent reduction in cost variance, indicating that the proposed severity level splits increase the explanatory power of the base MS–DRG in capturing differences in expected cost between the proposed MS–DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the

IPPS payment system. The following table reflects our simulation for the proposed new MS–DRGs with a three-way severity level split. Our findings represent what we would expect under the proposed modifications and proposed new MS–DRGs, based on claims data in the FY 2019 MedPAR file.

Proposed new MS-DRG	Number of Cases	Average Length of Stay	Average Costs
Proposed new MS-DRG 140 Major Head and Neck Procedures with MCC	620	9.1	$29,441
Proposed new MS-DRG 141 Major Head and Neck Procedures with CC	2,349	4.4	$16,229
Proposed new MS-DRG 142 Major Head and Neck Procedures without CC/MCC	1,273	2.7	$11,816
Proposed new MS-DRG 143 Other Ear, Nose, Mouth, and Throat O.R. Procedures with MCC	631	7.9	$20,126
Proposed new MS-DRG 144 Other Ear, Nose, Mouth, and Throat O.R. Procedures with CC	1,414	4.3	$12,523
Proposed new MS-DRG 145 Other Ear, Nose, Mouth, and Throat O.R. Procedures without CC/MCC	986	2.4	$9,026

We are proposing to create two new base MS–DRGs, 140 and 143, with a three-way severity level split for proposed new MS–DRGs 140, 141, and 142 (Major Head and Neck Procedures with MCC, with CC, and without CC/MCC, respectively) and proposed new MS–DRGs 143, 144, and 145 (Other Ear, Nose, Mouth And Throat O.R. Procedures with MCC, with CC, and without CC/MCC, respectively).

We refer the reader to Table 6P.2a and Table 6P.2b for the list of procedure codes we are proposing for reassignment from MS–DRGs 129, 130, 131, 132, 133, and 134 to each of the proposed new MS–DRGs. As noted, we are also proposing the removal of procedure codes 00J00ZZ and 0WJ10ZZ, and the 338 procedure codes listed in Table 6P.2c from the logic for MDC 03.

We note that discussion of the surgical hierarchy for the proposed modifications is discussed in section II.D.15. of this proposed rule.

5. MDC 5 (Diseases and Disorders of the Circulatory System)

a. Left Atrial Appendage Closure (LAAC)

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49363 through 49367) we finalized our proposal to create two new MS–DRGs to classify percutaneous intracardiac procedures. Specifically, we created MS–DRGs 273 and 274 (Percutaneous Intracardiac Procedures with and without MCC, respectfully) for cases reporting procedure codes describing cardiac ablation and other percutaneous intracardiac procedures. In that discussion, as FY 2016 was the first year of our transition from the ICD–9 based MS–DRGs to the ICD–10 based MS–DRGs, we provided a list of the ICD–9–CM procedure codes that identify and describe the cardiac ablation procedures and other percutaneous intracardiac procedures that were the subject of that MS–DRG classification change request, one of which was ICD–9–CM procedure code 37.90 (Insertion of left atrial appendage device).

Separately, we also discussed a request we received for new technology add-on payments for the WATCHMAN™ Left Atrial Appendage Closure (LAAC) device (80 FR 49480 through 49488). In that discussion, we noted that effective October 1, 2004 (FY 2005), ICD–9–CM procedure code 37.90 (Insertion of left atrial appendage device) was created to identify and describe procedures using the WATCHMAN™ Left Atrial Appendage (LAA) Closure Technology and that under ICD–10–PCS, procedure code 02L73DK (Occlusion of left atrial appendage with intraluminal device, percutaneous approach) is the comparable translation. We also noted that at the time of the new technology request, under the ICD–9 based MS–DRGs, procedure code 37.90 was assigned to MS–DRGs 250 and 251 (Percutaneous Cardiovascular Procedures without Coronary Artery Stent with MCC and without MCC, respectively). We further noted that, as stated previously, we finalized our proposal to assign procedures performed within the heart chambers using intracardiac techniques, including those identified by ICD–9–CM procedure code 37.90, and its comparable ICD–10–PCS code translations (that specifically identify a percutaneous or percutaneous endoscopic approach), including 02L73DK, to new MS–DRGs 273 and 274.

For this FY 2021 IPPS/LTCH PPS proposed rule, we received two separate, but related requests involving the procedure codes that describe the technology that is utilized in the performance of LAAC procedures. The first request was to reassign ICD–10–PCS procedure code 02L73DK (Occlusion of left atrial appendage with intraluminal device, percutaneous approach) that identifies the WATCHMAN™ Left Atrial Appendage Closure (LAAC) device, from MS–DRG 274 (Percutaneous Intracardiac Procedures without MCC) to MS–DRG 273 (Percutaneous Intracardiac Procedures with MCC) and revise the title for MS–DRG 273 to ''Percutaneous Intracardiac Procedures with MCC or Major Device Implant for Left Atrial Appendage Closure Procedures''. Cases involving LAAC procedures with a percutaneous or percutaneous endoscopic approach, including cases reporting ICD–10–PCS procedure code 02L73DK, are currently assigned to MS–DRGs 273 and 274.

According to the requestor's analysis, the average cost for LAAC procedures reporting ICD–10–PCS procedure code 02L73DK is $3,405 higher than the average cost for all cases in MS–DRG 274. The requestor stated that based on its analysis, this requested reassignment would have minimal impact on MS–DRGs 273 and 274 and would ensure adequate payments and better resource

coherency. The requestor stated that cases reporting procedure codes describing a LAAC procedure with procedure code 02L73DK within MS–DRG 274 are more clinically similar and costs are more closely aligned to cases within MS–DRG 273.

We examined claims data from the September 2019 update of the FY 2019 MedPAR file for MS–DRGs 273 and 274 to identify cases reporting ICD–10–PCS procedure code 02L73DK. Our findings are shown in the following table.

MS-DRG	ICD-10-PCS Code	Number of Cases	Average Length of Stay	Average Costs
273	All Cases	7,048	6.1	$28,100
	02L73DK	1,126	2.7	$29,504
274	All Cases	24,319	2.0	$24,048
	02L73DK	13,423	1.2	$25,846

In MS–DRG 273, we found a total of 7,048 cases with an average length of stay of 6.1 days and average costs of $28,100. Of those 7,048 cases, there were 1,126 cases reporting ICD–10–PCS procedure code 02L73DK, with an average length of stay of 2.7 days and average costs of $29,504. In MS–DRG 274, we found a total of 24,319 cases with an average length of stay of 2.0 days and average costs of $24,048. Of those 24,319 cases, there were 13,423 cases reporting ICD–10–PCS procedure code 02L73DK, with an average length of stay of 1.2 days and average costs of $25,846.

The data analysis demonstrates that the average costs of the cases reporting procedure code 02L73DK in MS–DRG 274 are slightly higher than the average costs of all the cases in MS–DRG 274 ($25,846 versus $24,048), with a difference of approximately $1,798, however, the average length of stay for cases reporting procedure code 02L73DK in MS–DRG 274 is shorter compared to all the cases in MS–DRG 274 (1.2 days versus 2 days). If we were to reassign cases reporting procedure code 02L73DK from MS–DRG 274 to MS–DRG 273, we would be assigning cases with an average length of stay of 1.2 days to a MS–DRG with an average length of stay of 6.1 days, which our clinical advisors did not support. The average costs of the cases reporting procedure code 02L73DK in MS–DRG 274 ($25,846) compared to the average costs of all the cases in MS–DRG 273 ($28,100) show a difference of $2,254. Our clinical advisors did not support reassigning the 13,423 cases reporting procedure code 02L73DK without an MCC from MS–DRG 274 to MS–DRG 273, which includes cases reporting a MCC, noting that it would impact the average costs for all cases in this MS–DRG. Lastly, our clinical advisors expressed concern regarding making proposed MS–DRG changes based on a specific, single technology (WATCHMAN™ Left Atrial Appendage Closure (LAAC) device), identified by only one unique procedure code versus considering proposed changes based on a group of related procedure codes that can be reported to describe that same type or class of technology, which is more consistent with the intent of the MS–DRGs. Therefore, for these reasons, we are not proposing to reassign cases reporting ICD–10–PCS procedure code 02L73DK (Occlusion of left atrial appendage with intraluminal device, percutaneous approach) from MS–DRG 274 to MS–DRG 273.

The second request was to create a new MS–DRG specific to all left atrial appendage closure (LAAC) procedures or to map all LAAC procedures to a different cardiovascular MS–DRG that has payment rates aligned with procedural costs. The requestor stated that by creating a new MS–DRG specific to all LAAC procedures or mapping all LAAC procedures to a different cardiovascular MS–DRG, the MS–DRG would more appropriately recognize the clinical characteristics and cost differences in LAAC cases.

The 9 ICD–10–PCS procedure codes that describe LAAC procedures and their corresponding MS–DRG assignment are listed in the following table.

ICD-10-PCS Code	MS-DRG	Description
02L70CK	250-251	Occlusion of left atrial appendage with extraluminal device, open approach
02L70DK	250-251	Occlusion of left atrial appendage with intraluminal device, open approach
02L70ZK	250-251	Occlusion of left atrial appendage, open approach
02L73CK	273-274	Occlusion of left atrial appendage with extraluminal device, percutaneous approach
02L73DK	273-274	Occlusion of left atrial Appendage with intraluminal device, percutaneous approach
02L73ZK	273-274	Occlusion of left atrial appendage, percutaneous approach
02L74CK	273-274	Occlusion of left atrial appendage with extraluminal device, percutaneous endoscopic approach
02L74DK	273-274	Occlusion of left atrial appendage with intraluminal device, percutaneous endoscopic approach
02L74ZK	273-274	Occlusion of left atrial appendage, percutaneous endoscopic approach

Currently, the MS–DRG assignments for these procedure codes are based on the surgical approach: open approach, percutaneous approach, or percutaneous endoscopic approach. Procedures describing an open approach are assigned to MS–DRGs 250 and 251 (Percutaneous Cardiovascular Procedures without Coronary Artery Stent with and without MCC, respectively); while procedures describing a percutaneous or percutaneous endoscopic approach are assigned to MS–DRGs 273 and 274 (Percutaneous Intracardiac Procedures

with and without MCC, respectfully). Of the nine listed ICD–10–PCS procedure codes, three (02L70CK, 02L70DK, and 02l70ZK) describe an open approach and are currently assigned to MS–DRG 250 and 251, and six (02L73CK, 02L73DK, 02L73ZK, 02L74CK, 02L74DK, 02L74ZK) describe a percutaneous or percutaneous endoscopic approach and are currently assigned to MS–DRG 273 and 274.

We examined claims data from the September 2019 update of the FY 2019 MedPAR file for cases reporting LAAC procedures with an open approach in MS–DRGs 250 and 251. Our findings are shown in the following table.

MS-DRGs 250 and 251 - LAAC Procedures with Open Approach

MS-DRG	ICD-10-PCS Code	Number of Cases	Average Length of Stay	Average Costs
250	All Cases	4,192	5.0	$18,807
	LAAC procedures with open approach	21	7.0	$44,012
251	All Cases	4,941	2.6	$12,535
	LAAC procedures with open approach	74	3.4	$22,711

In MS–DRG 250, we found a total of 4,192 cases with an average length of stay of 5.0 days and average costs of $18,807. Of those 4,192 cases, there were 21 cases reporting a LAAC procedure with an open approach, with an average length of stay of 7.0 days and average costs of $44,012. In MS–DRG 251, we found a total of 4,941 cases with an average length of stay of 2.6 days and average costs of $12,535. Of those 4,941 cases, there were 74 cases reporting a LAAC procedure with an open approach, with an average length of stay of 3.4 days and average costs of $22,711. The analysis shows that the cases reporting a LAAC procedure with an open approach in MS–DRGs 250 and 251 have higher average costs compared to all cases in MS–DRGs 250 and 251 ($44,012 versus $18,807 and $22,711 versus $12,535, respectively). The analysis also shows that the average length of stay for cases reporting a LAAC procedure with an open approach in MS–DRGs 250 and 251 is longer compared to all cases in MS–DRGs 250 and 251 (7.0 days versus 5.0 days and 3.4 days versus 2.6 days, respectively). Overall, there were a total of 95 (21+74) cases reporting a LAAC procedure with an open approach in MS–DRGs 250 and 251 with an average length of stay of 4.2 days and average costs of $27,420.

Based on the results of the claims data described previously, we conducted further analysis for the 95 cases reporting a LAAC procedure with an open approach in MS–DRGs 250 and 251 to determine if there were additional factors that may be contributing to the higher average costs and longer length of stay. Of those 95 cases, we found a total of 20 cases in which there was another O.R. procedure reported on the claim that is also currently assigned to MS–DRGs 250 and MS–DRG 251 and believed to be influencing the average costs and average length of stay, as shown in the following tables.

MS-DRG 250 List of O.R. Procedures Reported with LAAC Procedure (02L70CK, 02L70DK or 02L70ZK)				
ICD-10-PCS Code	**Description**	**Number of Cases**	**Average Length of Stay**	**Average Costs**
02UX0JZ	Supplement thoracic aorta, ascending/arch with synthetic substitute, open approach	2	10.0	$62,770
04U00JZ	Supplement abdominal aorta with synthetic substitute, open approach	1	7.0	$20,650
06H03DZ	Insertion of intraluminal device into inferior vena cava, percutaneous approach	1	4.0	$22,837
06JY4ZZ	Inspection of lower vein, percutaneous endoscopic approach	1	4.0	$20,772
0BNL4ZZ	Release left lung, percutaneous endoscopic approach	1	12.0	$55,375
0JH602Z	Insertion of monitoring device into chest subcutaneous tissue and fascia, open approach	1	9.0	$28,333
0WJC0ZZ	Inspection of mediastinum, open approach	1	15.0	$235,720
	Total	8	8.9	$63,653

As shown in the table, for MS–DRG 250, there were a total of 8 cases reporting another O.R. procedure with a LAAC procedure with an open approach with an average length of stay of 8.9 days and average costs of $63,653. The data shows that the average length of stay for these 8 cases range from 4.0 days to 15.0 days and the average costs range from $20,650 to $235,720.

Overall, the data demonstrates that the 8 cases reporting another O.R. procedure with a LAAC procedure with an open approach in MS–DRG 250 have a longer length of stay (8.9 days versus 7 days) and higher average costs ($63,653 versus $44,012) compared to all 21 cases reporting a LAAC procedure with an open approach in MS–DRG 250.

MS-DRGs 251 List of O.R. Procedures Reported with LAAC Procedure (02L70CK, 02L70DK or 02L70ZK)				
ICD-10-PCS Code	**Description**	**Number of Cases**	**Average Length of Stay**	**Average Costs**
01580ZZ	Destruction of thoracic nerve, open approach	1	1.0	$16,648
015L0ZZ	Destruction of thoracic sympathetic nerve, open approach	1	3.0	$34,074
02JA0ZZ	Inspection of heart, open approach	2	7.0	$39,326
02JA4ZZ	Inspection of heart, percutaneous endoscopic approach	1	4.0	$17,070
02JY0ZZ	Inspection of great vessel, open approach	1	5.0	$21,002
02PA0MZ	Removal of cardiac lead from heart, open approach	1	2.0	$12,767
02S00ZZ	Reposition coronary artery, one artery, open approach	1	11.0	$89,682
03UL0KZ	Supplement left internal carotid artery with nonautologous tissue substitute, open approach	1	9.0	$20,229
0BNP0ZZ	Release left pleura, open approach	1	18.0	$40,720
0W3D0ZZ	Control bleeding in pericardial cavity, open approach	1	9.0	$36,820
0WJC4ZZ	Inspection of mediastinum, percutaneous endoscopic approach	1	2.0	$11,052
	Total	12	6.5	$31,560

As shown in the table, for MS–DRG 251, there were a total of 12 cases reporting another O.R. procedure with a LAAC procedure with an open approach with an average length of stay of 6.5 days and average costs of $31,560. The data shows that the average length of stay for these 12 cases range from 1.0 day to 18.0 days and the average costs range from $11,052 to $89,682.

Overall, the data demonstrates that the 12 cases reporting another O.R. procedure with a LAAC procedure with an open approach in MS–DRG 251 have a longer average length of stay (6.5 days versus 3.4 days) and higher average costs ($31,560 versus $22,711) compared to all 74 cases reporting a LAAC procedure with an open approach in MS–DRG 251. The results of our claims analysis for the 20 cases reporting a LAAC procedure with an open approach and another O.R. procedure in MS–DRGs 250 and 251 indicate that the longer average length of stay and higher average costs of the 95 cases reporting a LAAC procedure with an open approach in MS–DRGs 250 and 251 may be attributed to the resource consumption of the additional O.R. procedures reported in the subset of 20 cases. The claims analysis also shows that the majority of the cases reporting a LAAC procedure with an open approach in MS–DRGs 250 and 251 (75 cases out of 95 cases) were without another O.R. procedure.

As noted in the discussion previously, with respect to the first LAAC MS–DRG request, our analysis of MS–DRG 273 found a total of 7,048 cases with an average length of stay of 6.1 days and average costs of $28,100 and our analysis of MS–DRG 274 found a total of 24,319 cases with an average length of stay of 2.0 days and average costs of $24,048. The average costs and average length of stay for cases reporting a LAAC procedure with an open approach in MS–DRGs 250 and 251 ($44,012 and $22,711, respectively) and (7.0 days and 3.4 days, respectively) appear to be generally more aligned with the average costs and average length of stay for all cases in MS–DRGs 273 and 274 ($28,100 and $24,048, respectively) and (6.1 days and 2.0 days, respectively) as compared to all cases in MS–DRGs 250 and 251 with average costs of $18,807 and $12,535, respectively and an average length of stay of 5.0 days and 2.6 days, respectively. In addition, as also noted previously, the second LAAC MS–DRG request was to create a new MS–DRG specific to all left atrial appendage closure (LAAC) procedures or to map all LAAC procedures to a different cardiovascular MS–DRG that has payment rates aligned with procedural costs. Our clinical advisors suggested that because our review of the cases reporting a LAAC procedure with an open approach in MS–DRGs 250 and 251 demonstrated that these procedures are primarily performed in the absence of another O.R. procedure and generally are not performed with a more intensive open chest procedure, that we should

evaluate cases reporting LAAC procedures with the other approaches in their assigned MS–DRGs.

We then examined claims data from the September 2019 update of the FY 2019 MedPAR file for cases reporting LAAC procedures with a percutaneous or percutaneous endoscopic approach in MS–DRGs 273 and 274. Our findings are shown in the following table.

MS-DRGs 273 and 274 - LAAC Procedures with Percutaneous or Percutaneous Endoscopic Approach

MS-DRG	ICD-10-PCS code	Number of Cases	Average Length of Stay	Average Costs
273	All Cases	7,048	6.1	$28,100
	LAAC procedures with percutaneous or percutaneous endoscopic approach	1,180	2.9	$29,591
274	All Cases	24,319	2.0	$24,048
	LAAC procedures with percutaneous or percutaneous endoscopic approach	13,774	1.2	$25,765

In MS–DRG 273, we found a total of 7,048 cases with an average length of stay of 6.1 days and average costs of $28,100. Of those 7,048 cases, there were 1,180 cases reporting a LAAC procedure with a percutaneous or percutaneous endoscopic approach, with an average length of stay of 2.9 days and average costs of $29,591. In MS–DRG 274, we found a total of 24,319 cases with an average length of stay of 2.0 days and average costs of $24,048. Of those 24,319 cases, there were 13,774 cases reporting a LAAC procedure with a percutaneous or percutaneous endoscopic approach, with an average length of stay of 1.2 days and average costs of $25,765.

The analysis shows that the cases reporting a LAAC procedure with a percutaneous or percutaneous endoscopic approach in MS–DRGs 273 and 274 have very similar average costs compared to all the cases in MS–DRGs 273 and 274 ($29,591 versus $28,100 and $25,765 versus $24,048, respectively). The analysis also shows that the average length of stay for cases reporting a LAAC procedure with a percutaneous or percutaneous endoscopic approach in MS–DRGs 273 and 274 is shorter compared to all cases in MS–DRGs 273 and 274 (2.9 days versus 6.1 days and 1.2 days versus 2.0 days, respectively). Overall, there were a total of 14,954 (1,180 + 13,774) cases reporting a LAAC procedure with a percutaneous or percutaneous endoscopic approach in MS–DRGs 273 and 274 with an average length of stay of 1.3 days and average costs of $26,067.

Our clinical advisors did not support creating a new MS–DRG for all LAAC procedures for FY 2021. Rather, our clinical advisors believe that ICD–10–PCS codes 02L70CK, 02L70DK, and 02L70ZK that describe a LAAC procedure with an open approach are more suitably grouped to MS–DRGs 273 and 274. They stated this reassignment would allow all LAAC procedures to be grouped together under the same MS–DRGs and would improve clinical coherence. We note that all the procedure codes describing LAAC procedures are designated as non-O.R. procedures that affect the MS–DRG to which they are assigned. Therefore, we are proposing to reassign ICD–10–PCS codes 02L70CK, 02L70DK, and 02L70ZK from MS–DRGs 250 and 251 (Percutaneous Cardiovascular Procedures without Coronary Artery Stent with and without MCC, respectively) to MS–DRGs 273 and 274 (Percutaneous Intracardiac Procedures with and without MCC, respectively).

b. Endovascular Cardiac Valve Replacement and Supplement Procedures

We received a request to revise MS–DRGs 266 and 267 (Endovascular Cardiac Valve Replacement and Supplement Procedures with and without MCC, respectively) by removing the current two-way severity level split and creating a base MS–DRG without any severity level splits. According to the requestor, patients treated with an endovascular cardiac valve replacement procedure have severe heart failure due to a valvular disorder, which may be documented as either an exacerbation of heart failure or as chronic severe heart failure.

The requestor noted that in the cases reporting an endovascular cardiac valve replacement procedure, a secondary diagnosis code describing the specific type of heart failure may be the only MCC reported on the claim and in instances where the heart failure diagnosis code is reported as the principal diagnosis on a claim, it is disregarded from acting as a MCC. In both scenarios, the requestor reported that the heart failure is treated with the endovascular cardiac valve replacement procedure, fluid balance, and medication.

The requestor also stated that providers are challenged in reaching a consensus regarding this subset of patients' symptoms that may be helpful in establishing a diagnosis for exacerbation of heart failure versus chronic severe heart failure and stated that a single, base MS–DRG would assist in the calculation of costs and charges more reliably, regardless of the diagnosis reported in combination with the endovascular cardiac valve replacement procedure.

We examined claims data from the September 2019 update of the FY 2019 MedPAR file for MS–DRGs 266 and 267. Our findings are shown in the following table.

MS-DRGs for Endovascular Cardiac Valve Replacement and Supplement Procedures			
MS-DRG	**Number of Cases**	**Average Length of Stay**	**Average Costs**
MS-DRG 266-All cases	19,012	5.3	$50,879
MS-DRG 267-All cases	27,084	2.1	$40,471

As shown in the table, there was a total of 19,012 cases with an average length of stay of 5.3 days and average costs of $50,879 in MS–DRG 266. For MS–DRG 267, there was a total of 27,084 cases with an average length of stay of 2.1 days and average costs of $40,471. To evaluate the request to create a single MS–DRG for cases reporting endovascular cardiac valve procedures, we conducted an analysis of base MS–DRG 266. This analysis includes 2 years of MedPAR claims data to compare the data results from 1 year to the next to avoid making determinations about whether additional severity levels are warranted based on an isolated year's data fluctuation and also, to validate that the established severity levels within a base MS–DRG are supported. Therefore, we reviewed the claims data for base MS–DRG 266 using the September 2018 update of the FY 2018 MedPAR file and the September 2019 update of the FY 2019 MedPAR file, which were used in our analysis of claims data for MS–DRG reclassification requests for FY 2020 and FY 2021. Our findings are shown in the table.

FY Data	Number of Cases	Number of Cases MCC	Number of Cases CC	Number of Cases Non CC	Average Costs No Split	Average Costs MCC	Average Costs CC	Average Costs Non CC	Average Costs MCC/CC combo	Average Costs CC/NonCC combo
2019	46,096	19,012	21,361	5,723	$44,764	$50,879	$40,589	$40,032	$45,435	$40,471
2018	43,382	18,383	19,924	5,075	$44,593	$50,312	$40,936	$38,234	$45,435	$40,387

As shown in the table, the data reflect that the criteria for a two-way split (''with MCC'' and ''without MCC'') are satisfied using both the data from the September 2018 update of the FY 2018 MedPAR file and the data from the September 2019 update of the FY 2019 MedPAR file: (1) At least 500 cases are in the MCC group and in the without MCC subgroup; (2) at least 5 percent of the cases in the MS–DRG are in the MCC group and in the without MCC subgroup; (3) at least a 20 percent difference in average costs between the MCC group and the without MCC group; (4) at least a $2,000 difference in average costs between the MCC group and the without MCC group; and (5) at least a 3-percent reduction in cost variance, indicating that the current severity level splits increase the explanatory power of the base MS–DRG in capturing differences in expected cost between the current MS–DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the IPPS payment system. Our clinical advisors also did not agree with the requestor's assertion that a single, base MS–DRG would assist in calculating costs more reliably. As shown in the claims data and stated previously, the criteria are satisfied for the current two-way split. We further note that the basis for the MS–DRGs is to better recognize severity and complexity of services, which is accomplished through the CC subgroups.

Based on the results of our analysis, for FY 2021, we are proposing to maintain the current structure of MS–DRGs 266 and 267 with a two-way severity level split and not create a single, base MS–DRG.

c. Insertion of Cardiac Contractility Modulation Device

We received a request to review the MS–DRG assignment for cases that identify patients who receive a cardiac contractility modulation (CCM) device system for congestive heart failure. CCM is indicated for patients with moderate to severe heart failure resulting from either ischemic or non-ischemic cardiomyopathy. CCM utilizes electrical signals which are intended to enhance the strength of the heart and overall cardiac performance. CCM delivery device systems consist of a programmable implantable pulse generator (IPG) and three leads which are implanted in the heart. One lead is implanted into the right atrium and the other two leads are inserted into the right ventricle. The lead in the right atrium detects atrial electric signals and transmits them to the IPG. The IPG, which is usually implanted into the subcutaneous pocket of the pectoral region and secured to the fascia with a non-absorbable suture, processes the atrial signal and generates the CCM signals which are transmitted to the right ventricle via the two ventricular leads. According to the requestor, MS–DRGs 222, 223, 224, 225, 226, and 227 (Cardiac Defibrillator Implant with and without Cardiac Catheterization with and without AMI/HF/Shock with and without MCC, respectively) include code combinations or ''code pairs'' describing the insertion of contractility modulation devices. Currently however, the MS–DRG GROUPER logic requires the combination of the CCM device codes and a left ventricular lead to map to MS–DRGs 222, 223, 224, 225, 226 and 227. The requestor stated the CCM device is contraindicated in patients with a left ventricular lead. Therefore, using the current V37 MS–DRG GROUPER logic, no case involving insertion of the CCM system can be appropriately mapped to MS–DRGs 222, 223, 224, 225, 226 and 227. Instead, the cases map to MS–DRG 245 (AICD Generator Procedures). According to the requestor, to date, the procedure has been performed on an outpatient basis, but it is expected that some Medicare patients will receive CCM devices on an inpatient basis. The requestor asked that CMS revise the MS–DRG GROUPER logic to group cases reporting the use of the CCM device appropriately.

The ICD–10–PCS procedure code pairs currently assigned to MS–DRGs

222, 223, 224, 225, 226 and 227 that identify the insertion of contractility modulation devices are shown in the following table:

ICD-10-PCS Code	Code Description
02HL0MZ	Insertion of cardiac lead into left ventricle, open approach
with	
0JH60AZ	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, open approach
02HL3MZ	Insertion of cardiac lead into left ventricle, percutaneous approach
with	
0JH60AZ	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, open approach
02HL4MZ	Insertion of cardiac lead into left ventricle, percutaneous endoscopic approach
with	
0JH60AZ	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, open approach
02HL0MZ	Insertion of cardiac lead into left ventricle, open approach
with	
0JH63AZ	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, percutaneous approach
02HL3MZ	Insertion of cardiac lead into left ventricle, percutaneous approach
with	
0JH63AZ	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, percutaneous approach
02HL4MZ	Insertion of cardiac lead into left ventricle, percutaneous endoscopic approach
with	
0JH63AZ	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, percutaneous approach
02HL0MZ	Insertion of cardiac lead into left ventricle, open approach
with	
0JH80AZ	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, open approach
02HL3MZ	Insertion of cardiac lead into left ventricle, percutaneous approach
with	
0JH80AZ	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, open approach
02HL4MZ	Insertion of cardiac lead into left ventricle, percutaneous endoscopic approach
with	
0JH80AZ	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, open approach
02HL0MZ	Insertion of cardiac lead into left ventricle, open approach
with	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, percutaneous
0JH83AZ	approach
02HL3MZ	Insertion of cardiac lead into left ventricle, percutaneous approach
with	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, percutaneous
0JH83AZ	approach
02HL4MZ	Insertion of cardiac lead into left ventricle, percutaneous endoscopic approach
with	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, percutaneous
0JH83AZ	approach

Based on our analysis of cases reporting ICD–10–PCS procedure codes for CCM device systems, we agree with the requestor that a procedure code pair for the insertion of a CCM device and right ventricular and/or right atrial lead does not exist in the logic for MS–DRGs 222, 223, 224, 225, 226 and 227. Our analysis indicates that the ICD–10–PCS procedure code combinations for right ventricular and/or right atrial lead insertion with insertion of contractility modulation devices were inadvertently excluded from MS–DRGs 222, 223, 224, 225, 226 and 227 as a result of replicating the ICD–9 based MS–DRGs.

We examined claims data from the September 2019 update of the FY 2019 MedPAR file for MS–DRG 245 and identified the subset of cases within MS–DRG 245 reporting procedure codes for the insertion of a rechargeable CCM device and the insertion of right ventricular and/or right atrium lead. We found zero cases in MS–DRG 245 reporting a procedure code combination that identifies the insertion of contractility modulation device and the insertion of a cardiac lead into the right ventricle and/or right atrium lead.

Our clinical advisors agree that insertion of a rechargeable CCM system always involves placement of a right-sided lead, and that the code combinations that currently exist in the MS–DRG GROUPER logic are considered clinically invalid. We again examined claims data from the September 2019 update of the FY 2019 MedPAR file for MS–DRGs 222, 223, 224, 225, 226 and 227 for this subset of cases to determine if there were any cases that reported one of the 12 clinically invalid code combinations that exist in the GROUPER logic. Because the combinations of codes that describe the insertion of a rechargeable CCM device and the insertion of left ventricular lead are considered clinically invalid procedures, we would not expect these code combinations to be reported in any claims data. We found zero cases across MS–DRGs 222, 223, 224, 225, 226 and 227 reporting the clinically invalid procedure combination that identifies the insertion of contractility modulation device and the insertion of a cardiac lead into the left ventricle.

While our analysis did not identify any cases reporting a procedure code combination for the insertion of contractility modulation device and the

insertion of a cardiac lead into right ventricle or right atrium, recognizing that it is expected that some Medicare patients will receive CCM devices on an inpatient basis, we are proposing to add the following 24 ICD–10–PCS code combinations to MS–DRGs 222, 223, 224, 225, 226 and 227. We are also proposing to delete the 12 clinically invalid code combinations from the GROUPER logic of MS–DRGs 222, 223, 224, 225, 226 and 227 that describe the insertion of contractility modulation device and the insertion of a cardiac lead into the left ventricle.

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ICD-10-PCS Code	Code Description
02HK0MZ with 0JH60AZ	Insertion of cardiac lead into right ventricle, open approach
	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, open approach
02HK3MZ with 0JH60AZ	Insertion of cardiac lead into right ventricle, percutaneous approach
	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, open approach
02HK4MZ with 0JH60AZ	Insertion of cardiac lead into right ventricle, percutaneous endoscopic approach
	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, open approach
02HK0MZ with 0JH63AZ	Insertion of cardiac lead into right ventricle, open approach
	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, percutaneous approach
02HK3MZ with 0JH63AZ	Insertion of cardiac lead into right ventricle, percutaneous approach
	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, percutaneous approach
02HK4MZ with 0JH63AZ	Insertion of cardiac lead into right ventricle, percutaneous endoscopic approach
	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, percutaneous approach
02HK0MZ with 0JH80AZ	Insertion of cardiac lead into right ventricle, open approach
	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, open approach
02HK3MZ with 0JH80AZ	Insertion of cardiac lead into right ventricle, percutaneous approach
	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, open approach
02HK4MZ with 0JH80AZ	Insertion of cardiac lead into right ventricle, percutaneous endoscopic approach
	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, open approach
02HK0MZ with 0JH83AZ	Insertion of cardiac lead into right ventricle, open approach
	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, percutaneous approach
02HK3MZ with 0JH83AZ	Insertion of cardiac lead into right ventricle, percutaneous approach
	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, percutaneous approach
02HK4MZ with 0JH83AZ	Insertion of cardiac lead into right ventricle, percutaneous endoscopic approach
	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, percutaneous approach
02H60MZ	Insertion of cardiac lead into right atrium, open approach

ICD-10-PCS Code	Code Description
with 0JH60AZ	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, open approach
02H63MZ with 0JH60AZ	Insertion of cardiac lead into right atrium, percutaneous approach
	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, open approach
02H64MZ with 0JH60AZ	Insertion of cardiac lead into right atrium, percutaneous endoscopic approach
	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, open approach
02H60MZ with 0JH63AZ	Insertion of cardiac lead into right atrium, open approach
	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, percutaneous approach
02H63MZ with 0JH63AZ	Insertion of cardiac lead into right atrium, percutaneous approach
	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, percutaneous approach
02H64MZ with 0JH63AZ	Insertion of cardiac lead into right atrium, percutaneous endoscopic approach
	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, percutaneous approach
02H60MZ with 0JH80AZ	Insertion of cardiac lead into right atrium, open approach
	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, open approach
02H63MZ with 0JH80AZ	Insertion of cardiac lead into right atrium, percutaneous approach
	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, open approach
02H64MZ with 0JH80AZ	Insertion of cardiac lead into right atrium, percutaneous endoscopic approach
	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, open approach
02H60MZ with 0JH83AZ	Insertion of cardiac lead into right atrium, open approach
	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, percutaneous approach
02H63MZ with 0JH83AZ	Insertion of cardiac lead into right atrium, percutaneous approach
	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, percutaneous approach
02H64MZ with 0JH83AZ	Insertion of cardiac lead into right atrium, percutaneous endoscopic approach
	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, percutaneous approach

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6. MDC 6 (Diseases and Disorders of the Digestive System): Acute Appendicitis

We received a request to add ICD–10–CM diagnosis code K35.20 (Acute appendicitis with generalized peritonitis, without abscess) to the list of complicated principal diagnoses that group to MS–DRGs 338, 339 and 340 (Appendectomy with Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) so that all ruptured/perforated appendicitis codes in MDC 06 (Diseases and Disorders of the Digestive System) group to MS–DRGs 338, 339, and 340. ICD–10–CM diagnosis code K35.20 currently groups to MS–DRGs 341, 342, and 343 (Appendectomy without Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). Under current coding conventions, the following inclusion term for subcategory

K35.2 (Acute appendicitis with generalized peritonitis) is: Appendicitis (acute) with generalized (diffuse) peritonitis following rupture or perforation of the appendix. The requestor also noted that diagnosis code K35.32 (Acute appendicitis with perforation and localized peritonitis, without abscess) currently groups to MS–DRGs 338, 339, and 340, however, diagnosis code K35.20 which describes a generalized, more extensive form of peritonitis does not. The requestor stated that ICD–10–CM diagnosis code K35.20 is the only ruptured appendicitis code not included in the list of complicated principal diagnosis codes for MS–DRGs 338, 339 and 340 and stated that it is clinically appropriate for all ruptured/perforated appendicitis diagnosis codes to group to MS–DRGs 338, 339 and 340.

We analyzed claims data from the September 2019 update of the FY 2019 MedPAR file for cases in MS–DRGs 341, 342, and 343 and claims reporting ICD–10–CM diagnosis code K35.20 as a principal diagnosis. Our findings are shown in the following table.

MS-DRG	ICD-10-CM Code	Number of Cases	Average Length of Stay	Average Costs
341	All cases	718	5.9	$17,270
	K35.20	62	7.8	$20,244
342	All cases	2,184	3.4	$10,611
	K35.20	183	4.2	$10,952
343	All cases	2,329	2.0	$8,298
	K35.20	137	2.6	$8,088

As shown in the table, we found a total of 718 cases with an average length of stay of 5.9 days and average costs of $17,270 in MS–DRG 341. Of those 718 cases, there were 62 cases reporting a principal diagnosis code of K35.20 with an average length of stay of 7.8 days, and average costs of $20,244. We found a total of 2,184 cases with an average length of stay of 3.4 days and average costs of $10,611 in MS–DRG 342. Of those 2,184 cases there were 183 cases reporting a principal diagnosis code of K35.20 with an average length of stay of 4.2 days, and average costs of $10,952. We found a total of 2,329 cases with an average length of stay of 2.0 days and average costs of $8,298 in MS–DRG 343. Of those 2,329 cases, there were 137 cases reporting a principal diagnosis code of K35.20 with an average length of stay of 2.6 days, and average costs of $8,088.

We also analyzed claims data from the September 2019 update of the FY 2019 MedPAR file for MS–DRGs 338, 339, and 340. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
338	685	8.1	$20,930
339	2,245	5.0	$12,705
340	1,840	2.9	$9,101

As shown in the table, we found a total of 685 cases with an average length of stay of 8.1 days and average costs of $20,930 in MS–DRG 338. We found a total of 2,245 cases with an average length of stay of 5.0 days and average costs of $12,705 in MS–DRG 339. We found a total of 1,840 cases, average length of stay 2.9 days, and average costs of $9,101 in MS–DRG 340.

Our clinical advisors agreed that the presence of an abscess would clinically determine whether a diagnosis of acute appendicitis would be considered a complicated principal diagnosis. As diagnosis code K35.20 is described as ''without'' an abscess, our clinical advisors recommended that it not be added to the list of principal diagnoses for MS–DRGS 338, 339, and 340 (Appendectomy with Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). We believe that while the average costs for cases reporting diagnosis code K35.20 are similar to the cases in MS–DRGs 338, 339, and 340, diagnosis codes describing acute appendicitis that do not indicate the presence of an abscess should remain in MS–DRGs 341, 342, and 343 (Appendectomy without Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) for clinical consistency. Therefore, we are not proposing to reassign diagnosis code K35.20 from MS–DRGs 341, 342, and 343 to MS–DRGs 338, 339, and 340.

As noted previously, the requestor pointed out that diagnosis K35.32 (Acute appendicitis with perforation and localized peritonitis, without abscess) currently groups to MS–DRGs 338, 339, and 340 (Appendectomy with Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). Therefore, we identified all the diagnosis codes describing acute appendicitis within the ICD–10–CM classification under subcategory K35.2 (Acute appendicitis with generalized peritonitis) and subcategory K35.3 (Acute appendicitis with localized

peritonitis) and reviewed their respective MS–DRG assignments for clinical coherence. The diagnosis codes in these subcategories are shown in the following table.

ICD-10-CM Code	Description
K35.20	Acute appendicitis with generalized peritonitis, without abscess
K35.21	Acute appendicitis with generalized peritonitis, with abscess
K35.30	Acute appendicitis with localized peritonitis, without perforation or gangrene
K35.31	Acute appendicitis with localized peritonitis and gangrene, without perforation
K35.32	Acute appendicitis with perforation and localized peritonitis, without abscess
K35.33	Acute appendicitis with perforation and localized peritonitis, with abscess

We analyzed claims data from the September 2019 update of the FY 2019 MedPAR file for cases reporting any one of the ICD–10–CM diagnosis codes as previously listed as a principal diagnosis in MS–DRGs 338, 339, 340, 341, 342, and 343. Our findings are shown in the following table.

ICD-10-CM Code	MS-DRG	Number of Cases	Average Length of Stay	Average Costs
K35.20	341	62	7.8	$20,244
	342	183	4.1	$10,952
	343	137	2.6	$8,088
K35.21	338	33	11.2	$26,267
	339	94	6.8	$15,490
	340	44	3.6	$9,364
K35.30	341	65	4.5	$13,458
	342	278	3.0	$9,176
	343	288	1.8	$7,250
K35.31	341	20	6.2	$15,826
	342	90	3.9	$10,176
	343	90	2.4	$7,664
K35.32	338	329	7.7	$19,775
	339	1221	4.5	$11,870
	340	1067	2.7	$8,903
K35.33	338	285	8.5	$22,342
	339	894	5.6	$13,523
	340	718	3.1	$9,373

As shown in the table, the diagnosis codes describing ''with abscess'' (K35.21 and K35.33) are currently assigned to MS–DRGs 338, 339, and 340. In addition, the diagnosis codes describing ''without abscess'' (K35.20, K35.30, and K35.31) are currently assigned to MS–DRGs 341, 342, and 343. Our clinical advisors believe that cases reporting ICD–10–CM diagnosis codes describing ''with abscess'' are associated with higher severity of illness and resource consumption because of extended lengths of stay and treatment with intravenous antibiotics. Therefore, our clinical advisors determined that diagnosis code K35.32 should also be assigned to MS–DRGs 341, 342, and 343 for clinical consistency.

Accordingly, we are proposing to reassign diagnosis code K35.32 to MS–DRGs 341, 342, and 343 (Appendectomy without Complicated Principal

Diagnosis with MCC, with CC, and without CC/MCC, respectively).

The ICD–10 MS–DRG Version 37 Definitions Manual currently lists the following ICD–10–CM diagnosis codes as Complicated Principal Diagnoses in MS–DRGs 338, 339, 340, 341, 342, and 343: C18.1 (Malignant neoplasm of appendix); C7A.020 (Malignant carcinoid tumor of the appendix); K35.21 (Acute appendicitis with generalized peritonitis, with abscess); K35.32 (Acute appendicitis with perforation and localized peritonitis, without abscess) and K35.33 (Acute appendicitis with perforation and localized peritonitis, with abscess). For the same reasons discussed previously, we are proposing to remove diagnosis code K35.32 from the complicated principal diagnosis list to be clinically consistent.

Therefore, for the reasons discussed, we are proposing to (1) maintain the current assignment of diagnosis code K35.20 (Acute appendicitis with generalized peritonitis, without abscess) in MS–DRGs 341, 342, and 343 (Appendectomy without Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively); (2) reassign diagnosis code K35.32 from MS–DRGs 338, 339, and 340 to MS–DRGs 341, 342, and 343; and (3) remove diagnosis code K35.32 from the complicated principal diagnosis list in MS–DRGs 338, 339, and 340 as listed in the ICD–10 MS–DRG Version 37 Definitions Manual.

7. MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)

a. Cervical Radiculopathy

We received a request to reassign ICD–10–CM diagnosis codes M54.11 (Radiculopathy, occipito-atlanto-axial region), M54.12, (Radiculopathy, cervical region) and M54.13 (Radiculopathy, cervicothoracic region) from MDC 01 (Diseases and Disorders of the Nervous System) to MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue). The requestor stated that when one of these diagnosis codes describing radiculopathy in the cervical/cervicothoracic area of the spine is reported as a principal diagnosis in combination with a cervical spinal fusion procedure code, the case currently groups to MDC 01 in MS–DRG 028 (Spinal Procedures with MCC), MS–DRG 029 (Spinal Procedures with CC or Spinal Neurostimulators), and MS–DRG 030 (Spinal Procedures without CC/MCC). The requestor acknowledged that radiculopathy results from nerve impingement, however, the requestor noted it typically also results from a musculoskeletal spinal disorder such as spondylosis or stenosis. According to the requestor, the underlying musculoskeletal cause should be reported as the principal diagnosis if documented. The requestor stated that when the medical record documentation to support a musculoskeletal cause is not available, cases reporting a cervical spinal fusion procedure with a principal diagnosis of cervical radiculopathy would be more consistent with other cervical spinal fusion procedures if they grouped to MDC 08 in MS–DRGs 471, 472, and 473 (Cervical Spinal Fusion with MCC, with CC, and without CC/MCC, respectively). The requestor stated that the following diagnosis codes describing radiculopathy of the thoracic and lumbar areas of the spine are currently assigned to MDC 08 and therefore, group appropriately to the spinal fusion MS–DRGs in MDC 08.

ICD-10-CM Code	Description
M54.14	Radiculopathy, thoracic region
M54.15	Radiculopathy, thoracolumbar region
M54.16	Radiculopathy, lumbar region
M54.17	Radiculopathy, lumbosacral region

The requestor is correct that when diagnosis codes M54.11, M54.12 or M54.13 are reported as a principal diagnosis in combination with a cervical spinal fusion procedure, the case currently groups to MDC 01 in MS–DRG 028, MS–DRG 029, and MS–DRG 030. This grouping occurs because the diagnosis codes describing radiculopathy in the cervical/cervicothoracic area of the spine are assigned to MDC 01 and the procedure codes describing a cervical spinal fusion procedure are assigned to MDC 01 in MS–DRGs 028, 029 and 030. The requestor is also correct that diagnosis codes describing radiculopathy of the thoracic and lumbar areas of the spine (M54.14, M54.15, M54.16 and M54.17) are currently assigned to MDC 08 and therefore, group to the spinal fusion MS–DRGs in MDC 08 consistent with the GROUPER logic definitions. The MS–DRGs that involve spinal fusion procedures of the cervical or lumbar regions that are currently assigned in MDC 01 and MDC 08 are listed in the following table.

MDC	MS-DRG	Description
01	028	Spinal Procedures with MCC
	029	Spinal Procedures with CC or Spinal Neurostimulators
	030	Spinal Procedures without CC/MCC
08	453	Combined Anterior/Posterior Spinal Fusion with MCC
	454	Combined Anterior/Posterior Spinal Fusion with CC
	455	Combined Anterior/Posterior Spinal Fusion without CC/MCC
	456	Spinal Fusion Except Cervical with Spinal Curvature Or Malignancy Or Infection Or Extensive Fusions with MCC
	457	Spinal Fusion Except Cervical with Spinal Curvature Or Malignancy Or Infection Or Extensive Fusions with CC
	458	Spinal Fusion Except Cervical with Spinal Curvature Or Malignancy Or Infection Or Extensive Fusions without CC/MCC
	459	Spinal Fusion Except Cervical with MCC
	460	Spinal Fusion Except Cervical without MCC
	471	Cervical Spinal Fusion with MCC
	472	Cervical Spinal Fusion with CC
	473	Cervical Spinal Fusion without CC/MCC

We refer the reader to the ICD–10 MS–DRG Version 37 Definitions Manual (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for the listed MS–DRGs.

We examined claims data from the September 2019 update of the FY 2019 MedPAR file for all cases in MS–DRGs 028, 029, and 030 and for cases reporting any one of the diagnosis codes describing radiculopathy of the cervical/cervicothoracic area of the spine (M54.11, M54.12, or M54.13) in combination with a cervical spinal fusion procedure. We refer the reader to Table 6P.1b associated with this proposed rule (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index/* for the list of procedure codes describing a cervical spinal fusion procedure. Our findings are shown in the following table.

Cervical Radiculopathy with Cervical Spinal Fusion Procedures				
MS-DRG		Number of Cases	Average Length of Stay	Average Costs
MS-DRG 028	All cases	2,105	11.9	$40,886
	Cases with principal diagnosis of cervical radiculopathy with cervical spinal fusion	22	8.2	$44,980
MS-DRG 029	All cases	3,574	6	$24,026
	Cases with principal diagnosis of cervical radiculopathy with cervical spinal fusion	176	2.6	$24,852
MS-DRG 030	All cases	1,338	3.1	$17,393
	Cases with principal diagnosis of cervical radiculopathy with cervical spinal fusion	166	1.7	$23,003

As shown in the table, there were a total of 2,105 cases with an average length of stay of 11.9 days and average costs of $40,866 in MS–DRG 028. Of those 2,105 cases, there were 22 cases reporting a principal diagnosis of cervical radiculopathy with a cervical spinal fusion procedure with an average length of stay of 8.2 days and average costs of $44,980. For MS–DRG 029, there were a total of 3,574 cases with an average length of stay of 6 days and average costs of $24,026. Of those 3,574 cases, there were 176 cases reporting a principal diagnosis of cervical

radiculopathy with a cervical spinal fusion procedure with an average length of stay of 2.6 days and average costs of $24,852. For MS–DRG 030, there were a total of 1,338 cases with an average length of stay of 3.1 days and average costs of $17,393. Of those 1,338 cases, there were 166 cases reporting a principal diagnosis of cervical radiculopathy with a cervical spinal fusion procedure with an average length of stay of 1.7 days and average costs of $23,003.

We also reviewed the claims data for MS–DRGs 471, 472, and 473. Our findings are shown in the following table.

MS-DRGs for Cervical Spinal Fusion Procedures			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 471- All cases	3,327	9	$36,941
MS-DRG 472- All cases	15,298	3.3	$22,539
MS-DRG 473- All cases	11,144	2	$18,748

As shown in the table, there were a total of 3,327 cases with an average length of stay of 9 days and average costs of $36,941 in MS–DRG 471. There were a total of 15,298 cases with an average length of stay of 3.3 days and average costs of $22,539 in MS–DRG 472. There were a total of 11,144 cases with an average length of stay of 2 days and average costs of $18,748 in MS–DRG 473.

Based on the claims data, the average costs of the cases reporting a principal diagnosis of cervical radiculopathy with a cervical spinal fusion procedure are consistent with the average costs of all the cases in MS–DRGs 028, 029, and 030 in MDC 01. We also note that the average costs of all the cases in MS–DRGs 028, 029, and 030 in MDC 01 are also comparable to the average costs of all the cases in MS–DRGs 471, 472, and 473, respectively; ($40,886 versus $36,941; $24,026 versus $22,539; and $17,393 versus $18,748).

Our clinical advisors do not support reassigning diagnosis codes M54.11, M54.12, and M54.13 that describe radiculopathy in the cervical/cervicothoracic area of the spine from MDC 01 to MDC 08 until further analysis of the appropriate assignment of these and other diagnosis codes describing radiculopathy. As the requestor pointed out, the diagnosis codes describing radiculopathy of the thoracic and lumbar areas of the spine (M54.14, M54.15, M54.16 and M54.17) are currently assigned to MDC 08. There are also two other codes to identify radiculopathy within the classification, diagnosis code M54.10 (Radiculopathy, site unspecified) and M54.18 (Radiculopathy, sacral and sacrococcygeal region), both of which are currently assigned to MDC 01. Our clinical advisors recommend maintaining the current assignment of diagnosis codes describing cervical radiculopathy in MDC 01 until further analysis of whether all the diagnosis codes describing radiculopathy of a specified or unspecified site should be assigned to the same MDC and if so, whether those codes should be assigned to MDC 01 or MDC 08. As part of this analysis, they also recommend soliciting further input from the public on the appropriate assignment for all of the diagnosis codes describing radiculopathy, including from professional societies and national associations for neurology and orthopedics. For these reasons, we are not proposing to reassign diagnosis codes M54.11, M54.12, and M54.13 from MDC 01 to MDC 08 at this time.

b. Hip and Knee Joint Replacements

We received a request to restructure the MS–DRGs for total joint arthroplasty that utilize an oxidized zirconium bearing surface implant in total hip replacement and total knee replacement procedures. According to the requestor, several international joint replacement registries, retrospective claims review, and published clinical studies show compelling short-term, mid-term and long-term clinical outcomes for patients receiving these implants. The requestor stated that without specific MS–DRGs, beneficiary access to these implants is restricted and the benefit to patients and cost savings cannot be recognized.

The requestor noted that effective October 1, 2017, new ICD–10–PCS procedure codes describing hip and knee replacement procedures with an oxidized zirconium bearing surface implant were established, which allow greater specificity and provide the ability to track costs and clinical outcomes for the patients who receive the implant. The requestor provided 3 options for CMS to consider as part of its request which are summarized in this section of this rule.

The first option provided by the requestor was to create a new MS–DRG by reassigning cases reporting a hip or knee replacement procedure with an oxidized zirconium bearing surface implant from MS–DRG 470 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC) to the suggested new MS–DRG. The requestor conducted its own analysis and noted that there were approximately 18,000 cases reporting a hip or knee replacement with an oxidized zirconium bearing surface implant and the average length of stay for these cases was shorter in comparison to the cases reporting hip and knee replacement procedures without an oxidized zirconium bearing surface implant. The requestor suggested that patients receiving an oxidized zirconium bearing surface implant may be walking earlier after surgery and the risk of infection may be reduced as a result of the shorter hospitalization.

The requestor stated that separating out these cases reporting the use of an oxidized zirconium bearing surface implant is clinically justified because the implants are designed for increased longevity. The requestor also stated that oxidized zirconium is an entirely distinct material from traditional ceramic or metal implants, as it is made through a unique thermal oxidation process which creates a ceramicised surface while maintaining the biocompatible zirconium alloy substrate. According to the requestor, this process creates an implant with the unique properties of both metals and ceramics: Durability, strength and friction resistance. Conversely, the requestor stated that cobalt chrome used in metal implants contains up to 143x

more nickel (<0.5% vs <0.0035%) than oxidized zirconium and that nickel is the leading cause of negative reactions in patients with metal sensitivities.

The requestor asserted that creating a new MS–DRG for hip and knee replacement procedures with an oxidized zirconium bearing surface implant would be a logical extension of the unique procedure codes that CMS finalized and stated that other countries have established higher government reimbursement for these implants to reflect the increased value of the technology. The requestor also asserted that multiple joint replacement registries have reported excellent hip replacement results, including a statistically significant 33 percent reduced risk of revision ($p<0.001$) for oxidized zirconium on highly cross-linked polyethylene (XLPE), from three months compared to the most common bearing surface of metal/XLPE.

Lastly, the requestor stated that multiple U.S. data sources, including Medicare claims, show strong short-term outcomes, reduced 30-day readmissions, fewer discharges to skilled nursing facilities (SNFs), shorter LOS, and more frequent discharges to home, resulting in less costly post-acute care.

The second option provided by the requestor was to create a new MS–DRG by reassigning all cases in MS–DRG 470 reporting a hip replacement procedure (excluding those with an oxidized zirconium bearing surface implant) with a principal diagnosis of hip fracture and all hip replacement procedures with an oxidized zirconium bearing surface implant, with or without a principal diagnosis of hip fracture to the suggested new MS–DRG. The requestor stated that based on its own analysis, this proposed new MS–DRG would have approximately 58,000 cases with an estimated relative weight between the current MS–DRGs for total joint arthroplasty (MS–DRGs 469 and 470) to reflect the increased resource consumption of total hip replacement procedures performed due to a hip fracture, while also reflecting a higher resource grouping for oxidized zirconium bearing surface implants used in total hip replacement procedures, and lastly, to reflect statistically significant reductions in revision of total hip replacement procedure rates.

The requestor also indicated that a new MS–DRG for total hip replacement procedures with a hip fracture would correspond to differentials recognized in the Comprehensive Care for Joint Replacement (CJR) program, which established a separate target 90-day episode price for total hip replacement procedures performed due to hip fracture cases, as these are typically higher severity patients with longer lengths of stay than hip replacement procedures absent a hip fracture.

The requestor conducted its own analysis of Medicare claims data (Q4 2017–Q3 2018) for total hip replacement procedures and compared cases with an oxidized zirconium bearing surface implant to cases without an oxidized zirconium bearing surface implant. The requestor reported that it found statistically reduced SNF costs, hospital length of stay, 90-day episode costs, and 55% decreased mortality at 180 days for the oxidized zirconium bearing surface implant cases. The requestor urged CMS to recognize this technology with a differentiated payment in the form of a new MS–DRG, based on its findings of excellent clinical outcomes for total hip replacement procedures that utilize an oxidized zirconium bearing surface implant.

The third option provided by the requestor was to reassign all cases reporting a total hip replacement procedure using an oxidized zirconium bearing surface implant with a principal diagnosis of hip fracture from MS–DRG 470 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC) to MS–DRG 469 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement). The requestor stated this option would maintain the two existing MS–DRGs for total joint arthroplasty and would only involve moving a small subset of cases (approximately 300) from MS–DRG 470 to MS–DRG 469.

The requestor acknowledged that the third option was more limited than the first two options, however, the requestor stated that it was the least disruptive since the two MS–DRGs and estimated relative weights would remain essentially the same. The requestor also stated that reassigning cases reporting a total hip replacement procedure using an oxidized zirconium bearing surface implant with a principal diagnosis of hip fracture from MS–DRG 470 to MS–DRG 469 would encourage hospitals to use these high-quality, proven implants.

The requestor also asserted that the third option focuses the suggested payment changes on the population of patients that benefit the most from the technology. According to the requestor, the analysis of Medicare claims data suggests that there is potential to improve care for the older population of patients who receive a total hip replacement by encouraging providers to use an oxidized zirconium bearing surface implant for hip fracture cases. In addition, the requestor stated that long-term Medicare solvency concerns impel consideration of incentives as a means to drive better outcomes at lower cost. Specifically, the requestor asserted that if all of the approximately 150,000 total hip replacement procedures performed annually in the U.S. for hip fracture achieved 90-day episode cost savings observed in Medicare claims for oxidized zirconium bearing surface implants, based on the requestor's analysis, potential annual savings of more than $650 million could be realized, in addition to longer-term savings achieved through reduced revisions.

The requestor also welcomed additional analysis by CMS of the claims data and consideration of alternative configurations that might better align patient severity, clinical value and payment.

As indicated by the requestor, October 1, 2017, new ICD–10–PCS procedure codes describing hip and knee replacement procedures with an oxidized zirconium bearing surface implant were created. The procedure codes are as follows:

ICD-10-PCS Code	Description
0SR9069	Replacement of right hip joint with oxidized zirconium on polyethylene synthetic substitute, cemented, open approach
0SR906A	Replacement of right hip joint with oxidized zirconium on polyethylene synthetic substitute, uncemented, open approach
0SR906Z	Replacement of right hip joint with oxidized zirconium on polyethylene synthetic substitute, open approach
0SRB069	Replacement of left hip joint with oxidized zirconium on polyethylene synthetic substitute, cemented, open approach
0SRB06A	Replacement of left hip joint with oxidized zirconium on polyethylene synthetic substitute, uncemented, open approach
0SRB06Z	Replacement of left hip joint with oxidized zirconium on polyethylene synthetic substitute, open approach
0SRC069	Replacement of right knee joint with oxidized zirconium on polyethylene synthetic substitute, cemented, open approach
0SRC06A	Replacement of right knee joint with oxidized zirconium on polyethylene synthetic substitute, uncemented, open approach
0SRC06Z	Replacement of right knee joint with oxidized zirconium on polyethylene synthetic substitute, open approach
0SRD069	Replacement of left knee joint with oxidized zirconium on polyethylene synthetic substitute, cemented, open approach
0SRD06A	Replacement of left knee joint with oxidized zirconium on polyethylene synthetic substitute, uncemented, open approach
0SRD06Z	Replacement of left knee joint with oxidized zirconium on polyethylene synthetic substitute, open approach

We examined claims data from the September 2019 update of the FY 2019 MedPAR file for MS–DRGs 469 and 470 where hip and knee replacement procedures are currently assigned for cases reporting the use of an oxidized zirconium bearing surface implant to address the three options provided by the requestor.

To evaluate the first option provided by the requestor, we analyzed the cases reporting a total hip or total knee replacement procedure with an oxidized zirconium bearing surface implant in MS–DRG 470 to determine if a new MS–DRG is warranted. To evaluate the second option provided by the requestor, we analyzed the cases reporting a total hip replacement procedure without an oxidized zirconium bearing surface implant with a principal diagnosis of hip fracture and cases reporting a total hip replacement procedure with an oxidized zirconium implant with or without a principal diagnosis of hip fracture in MS–DRG 470 to determine if a new MS–DRG is warranted. We refer the reader to Table 6P.1c for a list of the procedure codes that describe a hip replacement without an oxidized zirconium bearing surface implant and to Table 6P.1e for a list of the diagnosis codes describing a hip fracture that were provided by the requestor for consideration of options 2 and 3. To evaluate the third option provided by the requestor, we analyzed the cases reporting a total hip replacement procedure with an oxidized zirconium bearing surface implant and a principal diagnosis of fracture in MS–DRG 470 to determine if the cases warrant reassignment to MS–DRG 469. Our findings are shown in the following table.

MS-DRGs for Total Hip and Knee Replacement Procedures with and without an Oxidized Zirconium Bearing Surface Implant with and without a Principal Diagnosis of Hip Fracture			
MS-DRG	**Number of Cases**	**Average Length of Stay**	**Average Costs**
MS-DRG 469-All cases	25,701	5.9	$22,126
MS-DRG 470-All cases	386,221	2.3	$14,326
MS-DRG 470-Cases reporting a total hip replacement or total knee replacement procedure with an oxidized zirconium bearing surface implant (Option 1)	18,898	2.1	$14,808
MS-DRG 470-Cases reporting a total hip replacement procedure without an oxidized zirconium bearing surface implant with a principal diagnosis of hip fracture (Option 2)	47,316	4.5	$16,077
MS-DRG 470-Cases reporting a total hip replacement procedure with an oxidized zirconium bearing surface implant with or without a principal diagnosis of hip fracture (Option 2)	7,241	1.9	$13,875
MS-DRG 470-Cases combined for Option 2	54,557	4.2	$15,785
MS-DRG 470-Cases reporting a total hip replacement procedure with an oxidized zirconium bearing surface implant with a principal diagnosis of hip fracture (Option 3)	316	4	$18,304

As shown in the table, there was a total of 25,701 cases with an average length of stay of 5.9 days and average costs of $22,126 in MS–DRG 469. For MS–DRG 470, there was a total of 386,221 cases with an average length of stay of 2.3 days and average costs of $14,326. Of those 386,221 cases in MS–DRG 470, there was a total of 18,898 cases reporting a total hip replacement or total knee replacement procedure with an oxidized zirconium bearing surface implant with an average length of stay of 2.1 days and average costs of $14,808; a total of 47,316 cases reporting a total hip replacement procedure with a principal diagnosis of hip fracture with an average length of stay of 4.5 days and average costs of $16,077; a total of 7,241 cases reporting a total hip replacement procedure with an oxidized zirconium bearing surface implant with or without a principal diagnosis of hip fracture with an average length of stay of 1.9 days and average costs of $13,875; and a total of 316 cases reporting a total hip replacement procedure with an oxidized zirconium bearing surface implant with a principal diagnosis of hip fracture with an average length of stay of 4 days and average costs of $18,304.

The data analysis performed to evaluate the first option provided by the requestor indicates that the 18,898 cases reporting a total hip replacement or total knee replacement procedure with an oxidized zirconium bearing surface implant in MS–DRG 470 have a similar average length of stay (2.1 days versus 2.3 days) and similar average costs ($14,808 versus $14,326) compared to all the cases in MS–DRG 470. The results are also consistent with the requestor's findings that there were approximately 18,000 cases reporting a hip or knee replacement with an oxidized zirconium bearing surface implant. Based on the claims analysis, our clinical advisors stated that the data does not support creating a new MS–DRG for these procedures. Our clinical advisors also believe that the characteristics of the patients and resources used for a case that involves a total hip replacement or total knee replacement procedure with an oxidized zirconium bearing surface implant are not clinically distinct from the characteristics of the patients and resources used for the cases reporting a total hip replacement or total knee replacement procedure without an oxidized zirconium bearing surface implant. Therefore, in consideration of the first option provided by the requestor, we are not proposing to create a new MS–DRG for cases reporting a total hip or knee replacement procedure with an oxidized zirconium bearing surface implant.

The data analysis performed to evaluate the second option provided by the requestor indicates that the 47,316 cases reporting a total hip replacement procedure without an oxidized zirconium bearing surface implant with a principal diagnosis of hip fracture have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 470 (4.5 days versus 2.3 days) and the average costs are higher when compared to all the cases in MS–DRG 470 ($16,077 versus

$14,326). For the 7,241 cases reporting a total hip replacement procedure with an oxidized zirconium bearing surface implant with or without a principal diagnosis of hip fracture, the average length of stay is shorter than the average length of stay for all the cases (1.9 days versus 2.3 days) and the average costs are slightly lower when compared to all the cases in MS–DRG 470 ($13,875 versus $14,326). Our analysis of the combined total number of cases identified for the second option provided by the requestor indicates that the 54,557 cases (47,316 + 7,241) have a longer average length of stay compared to the average length of stay for all the cases in MS–DRG 470 (4.2 days versus 2.3 days) and the average costs are slightly higher ($15,785 versus $14,326) when compared to all the cases in MS–DRG 470. The results are also consistent with the requestor's findings that there were approximately 58,000 cases reporting a total hip replacement procedure without an oxidized zirconium bearing surface implant with a principal diagnosis of hip fracture or a total hip replacement procedure with an oxidized zirconium bearing surface implant with or without a principal diagnosis of hip fracture. Our clinical advisors believe that the data does not support creating a new MS–DRG for the subset of cases as suggested by the requestor. They noted the variation in the volume (47,316 cases and 7,241 cases), average length of stay (4.5 days and 1.9 days), and the average costs ($16,077 and $13,875) for each subset of option 2 and that the total average cost for the combined cases identified for the second option ($15,785) is very similar to the costs of all the cases in MS–DRG 470 ($14,326). Therefore, in consideration of the second option provided by the requestor, we are not proposing to create a new MS–DRG for cases reporting a total hip replacement procedure without an oxidized zirconium bearing surface implant with a principal diagnosis of hip fracture and cases reporting a total hip replacement procedure with an oxidized zirconium implant with or without a principal diagnosis of hip fracture.

The data analysis performed to evaluate the third option provided by the requestor indicates that the 316 cases reporting a total hip replacement procedure with an oxidized zirconium bearing surface implant with a principal diagnosis of hip fracture have a longer average length of stay (4.0 days versus 2.3 days) and higher average costs ($18,304 versus $14,326) compared to all the cases in MS–DRG 470. The results are also consistent with the requestor's findings that there were approximately 300 cases reporting a total hip replacement procedure with an oxidized zirconium bearing surface implant with a principal diagnosis of hip fracture. Our clinical advisors noted that while the data shows a longer length of stay and higher average costs for these cases under option 3, the analysis of the cases reporting a total hip replacement procedure without an oxidized zirconium bearing surface implant with a principal diagnosis of hip fracture under option 2 also demonstrated a longer length of stay and higher average costs. They therefore recommended we conduct further review specifically of those cases reporting a total hip replacement procedure with a principal diagnosis of hip fracture, with or without an oxidized zirconium bearing surface implant.

Based on the advice of our clinical advisors and in connection with the request for CMS to examine the claims data and consider alternative configurations, we performed additional analysis of those cases reporting a total hip replacement procedure with a principal diagnosis of hip fracture for both MS–DRGs 469 and 470. The procedure codes for the hip replacement procedures included in this additional analysis are displayed in Table 6P.1d and the diagnosis codes for hip fracture included in this additional analysis are displayed in Table 6P.1e. Our findings are shown in the following table.

MS-DRGs for Total Hip and Knee Replacement Procedures with a Principal Diagnosis of Hip Fracture

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 469-All cases	25,701	5.9	$22,126
MS-DRG 469 – Cases reporting a total hip replacement procedure with a principal diagnosis of hip fracture	14,163	7.2	$21,951
MS-DRG 470-All cases	386,221	2.3	$14,326
MS-DRG 470- Cases reporting a total hip replacement procedure with a principal diagnosis of hip fracture	47,632	4.5	$16,092

As shown in the table, there was a total of 14,163 cases reporting a total hip replacement procedure with a principal diagnosis of hip fracture with an average length of stay of 7.2 days and average costs of $21,951 in MS–DRG 469. There was a total of 47,632 cases reporting a total hip replacement procedure with a principal diagnosis of hip fracture with an average length of stay of 4.5 days and average costs of $16,092 in MS–DRG 470. The average length of stay for the cases reporting a total hip replacement procedure with a principal diagnosis of hip fracture in MS–DRGs 469 and 470 were longer (7.2 days versus 5.9 days and 4.5 versus 2.3 days, respectively) compared to all the cases in their assigned MS–DRGs. The average costs of the cases reporting a total hip replacement procedure with a principal diagnosis of hip fracture in MS–DRG 469 were approximately $175 less when compared to the average costs of all

cases in MS–DRG 469 ($21,951 versus $22,126) and slightly more for MS–DRG 470 ($16,092 versus $14,326). Our clinical advisors support differentiating the cases reporting a total hip replacement procedure with a principal diagnosis of hip fracture from those cases without a hip fracture by assigning them to a new MS–DRG. They noted that clinically, individuals who undergo hip replacement following hip fracture tend to require greater resources for effective treatment than those without hip fracture. They further noted that the increased complexity associated with hip fracture patients can be attributed to the post traumatic state and the stress of pain, possible peri-articular bleeding, and the fact that this subset of patients, most of whom have fallen as the cause for their fracture, may be on average more frail than those who require hip replacement because of degenerative joint disease.

We applied the criteria to create subgroups in a base MS–DRG as discussed in section II.D.1.b. of this FY 2021 IPPS/LTCH PPS proposed rule. As shown in the table that follows, a three-way split of this base MS–DRG failed to meet the criterion that there be at least a 20% difference in average costs between the CC and NonCC subgroup and also failed to meet the criterion that there be at least a $2,000 difference in average costs between the CC and NonCC subgroup. The following table illustrates our findings.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
With MCC	14,163	7.2	$21,951
With CC	34,287	4.7	$16,500
Without CC/MCC	13,345	3.8	$15,042

We then applied the criteria for a two-way split for the ''with MCC and without MCC'' subgroups and found that all five criteria were met. For the proposed new MS–DRGs, there is at least (1) 500 cases in the MCC subgroup and 500 cases in the without MCC subgroup; (2) 5 percent of the cases in the MCC group and 5 percent in the without MCC subgroup; (3) a 20 percent difference in average costs between the MCC group and the without MCC group; (4) a $2,000 difference in average costs between the MCC group and the without MCC group; and (5) a 3-percent reduction in cost variance, indicating that the proposed severity level splits increase the explanatory power of the base MS–DRG in capturing differences in expected cost between the proposed MS–DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the IPPS payment system. The following table illustrates our findings.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
With MCC	14,163	7.2	$21,951
Without CC/MCC	47,632	4.5	$16,092

For FY 2021, we are proposing to create new MS–DRG 521 (Hip Replacement with Principal Diagnosis of Hip Fracture with MCC) and new MS–DRG 522 (Hip Replacement with Principal Diagnosis of Hip Fracture without MCC). We refer the reader to Table 6P.1d for the list of procedure codes describing hip replacement procedures and to Table 6P.1e for the list of diagnosis codes describing hip fracture diagnoses that we are proposing to define in the logic for these proposed new MS–DRGs.

We also note that the Comprehensive Care for Joint Replacement (CJR) model includes episodes triggered by MS–DRG 469 with hip fracture and MS–DRG 470 with hip fracture. Given the proposal to create proposed new MS–DRG 521 and MS–DRG 522, we seek comment on the effect this proposal would have on the CJR model and whether to incorporate MS–DRG 521 and MS–DRG 522, if finalized, into the CJR model's proposed extension to December 31, 2023. As discussed in the CJR proposed rule ''Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing'' (85 FR 10516), we proposed to extend the duration of the CJR model. This extension, if finalized, would revise certain aspects of the CJR model including, but not limited to, the episode of care definition, the target price calculation, the reconciliation process, the beneficiary notice requirements and the appeals process. Additionally, the CJR proposed rule would allow time to test the proposed changes by extending the length of the CJR model through December 31, 2023, for certain participant hospitals. The comment period for the CJR proposed rule closes on June 23, 2020 (85 FR 22978).

8. MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract)

a. Kidney Transplants

We received two separate but related requests to review the MS–DRG assignment for procedures describing the transplantation of kidneys. The first request was to designate kidney transplants as a Pre-MDC MS–DRG in the same manner that other organ transplants are. The requestor performed its own analysis and stated that it found that cases with a principal diagnosis from MDC 05 (Diseases and Disorders of the Circulatory System), for example I13.2 (Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease), reported with a kidney transplant from

MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract), grouped to MS–DRG 981 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC). The requestor stated it did not appear appropriate that a kidney transplant would group to MS–DRG 981 when diagnosis code I13.2 is a legitimate principal diagnosis for this procedure. This requestor also suggested that if there was a proposal for designating the MS–DRG for kidney transplants as a Pre-MDC MS–DRG, that a severity level split should also be proposed.

As discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42128 through 42129), during our review of cases that group to MS–DRGS 981 through 983, we noted that when procedures describing transplantation of kidneys (ICD–10–PCS procedure codes 0TY00Z0 (Transplantation of right kidney, allogeneic, open approach) and 0TY10Z0 (Transplantation of left kidney, allogeneic, open approach) are reported in conjunction with ICD–10–CM diagnosis codes in MDC 05 (Diseases and Disorders of the Circulatory System), the cases group to MS–DRGs 981 through 983. For the reasons discussed, we proposed to add ICD–10–PCS procedure codes 0TY00Z0 and 0TY10Z0 to MS–DRG 264 in MDC 05. As summarized in the FY 2020 IPPS/LTCH PPS final rule, commenters opposed our proposal to add ICD–10–PCS procedure codes 0TY00Z0 and 0TY10Z0 to MS–DRG 264 in MDC 05. Commenters suggested that CMS instead assign these cases to MS–DRG 652, noting that the length of stay for the vast majority of kidney transplant cases involving serious cardiac conditions approximates the length of stay for kidney transplants in general. After consideration of public comments, we did not finalize our proposal to add ICD–10–PCS procedure codes 0TY00Z0 and 0TY10Z0 to MS–DRG 264 in MDC 05. We stated that we believed it would be appropriate to take additional time to review the concerns raised by commenters consistent with the President's Executive Order on Advancing American Kidney Health (see *https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/*). Accordingly, cases reporting a principal diagnosis in MDC 05 with a procedure describing kidney transplantation (that is, procedure code 0TY00Z0 or 0TY10Z0) continue to group to MS–DRGs 981 through 983 under the ICD–10 MS–DRGs Version 37, effective October 1, 2019.

In response to these public comments and the request we received on this topic for FY 2021 consideration, we examined claims data from the September 2019 update of the FY 2019 MedPAR file for MS–DRG 652. In MS–DRG 652, there were 11,324 cases reporting one of the procedure codes listed describing a kidney transplant procedure, with an average length of stay of 6 days and average costs of $25,424.

ICD-10-PCS Code	Code Description
0TY00Z0	Transplantation of right kidney, allogeneic, open approach
0TY00Z1	Transplantation of right kidney, syngeneic, open approach
0TY00Z2	Transplantation of right kidney, zooplastic, open approach
0TY10Z0	Transplantation of left kidney, allogeneic, open approach
0TY10Z1	Transplantation of left kidney, syngeneic, open approach
0TY10Z2	Transplantation of left kidney, zooplastic, open approach

We then analyzed claims data for cases reporting one of the procedure codes listed describing the transplantation of kidney reported in MS–DRGs 981, 982, and 983. We did not find any such cases in MS–DRG 983.

MS-DRGs 981 and 982: Cases Reporting Procedures Describing Kidney Transplants			
ICD-10-PCS codes	Number of Cases	Average Length of Stay	Average Costs
0TY00Z0	264	6.7	$27,344
0TY00Z1	2	19.5	$173,011
0TY10Z0	99	6.5	$25,254
0TY10Z1	1	13	$37,803

Of the 366 cases reporting procedures describing kidney transplants in MS–DRGs 981 and 982, all of the cases reported a principal diagnosis from MDC 05. The diagnoses reported are reflected in the table.

MDC 05 Principal Diagnoses Reported with Procedure Codes for Kidney Transplant in MS-DRGs 981 and 982				
ICD-10-CM Code	**Description**	**Number of Times Reported**	**Average Length of Stay**	**Average Costs**
I11.0	Hypertensive heart disease with heart failure	1	5.0	$15,782
I13.0	Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease	5	5.9	$24,236
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease	358	6.2	$27,204
I21.4	Non-ST elevation (NSTEMI) myocardial infarction	1	6.0	$22,355
I77.89	Other specified disorders of arteries and arterioles	1	4.0	$34,358

Our clinical advisors reviewed these data. As indicated previously, in MS–DRG 652, there were 11,324 cases reporting one of the procedure codes listed describing a kidney transplant procedure, with an average length of stay of 6 days and average costs of $25,424. Our clinical advisors noted that the average costs for cases reporting transplantation of kidney with a diagnosis from MDC 05 listed previously are generally similar to the average costs of cases in MS–DRG 652. The diagnoses assigned to MDC 05 reflect conditions associated with the circulatory system. Our clinical advisors agreed that although these diagnoses might also be a reasonable indication for kidney transplant procedures, it would not be appropriate to move these diagnoses into MDC 11 because it could inadvertently cause cases reporting these same MDC 05 diagnoses with a circulatory system procedure to be assigned to an unrelated MS–DRG.

To further examine the impact of moving MDC 05 diagnoses into MDC 11, we analyzed claims data for cases reporting a circulatory system O.R. procedure and MDC 05 ICD–10–CM diagnosis code I13.2 (Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease). Diagnosis code I13.2 was selected since this diagnosis was the MDC 05 diagnosis most frequently reported with kidney transplant procedures. Our findings are reflected in the following table:

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Cases Reporting Circulatory System O.R. Procedures with a Principal Diagnosis of I13.2				
MS-DRG	Description	Number of Cases	Average Length of Stay	Average Costs
215	Other Heart Assist System Implant	66	15.3	$92,229
216	Cardiac Valve And Other Major Cardiothoracic Procedures With Cardiac Catheterization with MCC	34	23.5	$101,406
219	Cardiac Valve And Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC	14	23.4	$83,807
222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock with MCC	64	11.8	$67,663
226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC	126	9.9	$55,107
227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC	2	7.5	$52,521
228	Other Cardiothoracic Procedures with MCC	48	16.0	$60,199
231	Coronary Bypass with PTCA with MCC	1	16.0	$122,757
233	Coronary Bypass with Cardiac Catheterization with MCC	38	20.8	$92,315
235	Coronary Bypass without Cardiac Catheterization with MCC	13	13.8	$53,786
239	Amputation For Circulatory System Disorders Except Upper Limb And Toe with MCC	71	18.0	$43,665
242	Permanent Cardiac Pacemaker Implant with MCC	140	13.0	$45,094
243	Permanent Cardiac Pacemaker Implant with CC	1	8.0	$47,133
245	AICD Generator Procedures	50	9.8	$49,604
246	Percutaneous Cardiovascular Procedures with Drug-Eluting Stent With MCC Or 4+ Arteries Or Stents	632	8.3	$31,550
248	Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent With MCC Or 4+ Arteries Or Stents	28	9.1	$30,088
250	Percutaneous Cardiovascular Procedures without Coronary Artery Stent with MCC	52	9.5	$26,888
252	Other Vascular Procedures with MCC	1,392	10.1	$27,495
253	Other Vascular Procedures with CC	5	5.6	$9,738
255	Upper Limb And Toe Amputation For Circulatory System Disorders with MCC	28	11.9	$23,691
258	Cardiac Pacemaker Device Replacement with MCC	8	4.1	$15,210
260	Cardiac Pacemaker Revision Except Device Replacement with MCC	22	8.9	$27,198
263	Vein Ligation And Stripping	3	11.0	$33,860
264	Other Circulatory System O.R. Procedures	1,185	10.4	$27,612

Cases Reporting Circulatory System O.R. Procedures with a Principal Diagnosis of I13.2				
MS-DRG	**Description**	**Number of Cases**	**Average Length of Stay**	**Average Costs**
265	AICD Lead Procedures	3	11.3	$30,528
266	Endovascular Cardiac Valve Replacement And Supplement Procedures with MCC	51	18.7	$88,325
268	Aortic And Heart Assist Procedures Except Pulsation Balloon with MCC	4	13.5	$40,885
270	Other Major Cardiovascular Procedures with MCC	223	13.7	$45,112
273	Percutaneous Intracardiac Procedures with MCC	62	9.9	$31,193
	Total Cases	4,366		

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As shown in the table, if we were to move diagnosis code I13.2 to MDC 11, 4,366 cases would be assigned to the surgical class referred to as ''unrelated operating room procedures'' as an unintended consequence. Therefore, as an alternate option, we are proposing to modify the GROUPER logic for MS–DRG 652 by allowing the presence of a procedure code describing transplantation of the kidney to determine the MS–DRG assignment independent of the MDC of the principal diagnosis in most instances. The logic for MDC 24 (Multiple Significant Trauma) and MDC 25 (Human Immunodeficiency Virus Infections) will remain unchanged, meaning there would be two exceptions to the proposed modification of the GROUPER logic for MS–DRG 652. If a principal diagnosis of trauma and at least two significant traumas of different body sites are present, the appropriate MS–DRG in MDC 24 would be assigned based on the principal diagnosis and procedures reported, instead of MS–DRG 652. Also, if either a principal diagnosis of HIV infection or a secondary diagnosis of HIV infection with a principal diagnosis of a significant HIV related condition are present, the appropriate MS–DRG in MDC 25 would be assigned based on the principal diagnosis and procedures reported instead of MS–DRG 652. The diagram found towards the end of this discussion illustrates how the proposed MS–DRG logic for MS–DRG 652 (Kidney Transplant) would function.

We recognize MS–DRG 652 is one of the only transplant MS–DRGs not currently defined as a Pre-MDC. Pre-MDCs were an addition to Version 8 of the Diagnosis Related Groups. This was the first departure from the use of principal diagnosis as the initial variable in DRG and subsequently MS–DRG assignment. For Pre-MDC DRGs, the initial step in DRG assignment is not the principal diagnosis, but instead certain surgical procedures with extremely high costs such as heart transplant, liver transplant, bone marrow transplant, and tracheostomies performed on patients on long-term ventilation. When added in Version 8, these types of services were viewed as being very resource intensive. Our clinical advisors have noted, however, that treatment practices have shifted since the inception of Pre-MDCs. The current proposed refinements to MS–DRG 652 represent the first step in investigating how we may consider introducing this concept of allowing certain procedures to affect the MS–DRG assignment regardless of the MDC from which the diagnosis is reported in the future, with the possibility of removing the Pre-MDC category entirely. In other words, we would consider having the resource intensive procedures currently assigned to the Pre-MDC MS–DRGs determine assignment to MS–DRGs within the clinically appropriate MDC. We are making concerted efforts to continue refining the ICD–10 MS–DRGs and we believe that it is important to include the Pre-MDC category as part of our comprehensive review.

In response to the request for a severity level split, since the request to designate kidney transplants as a Pre-MDC MS–DRG did not involve a revision of the existing GROUPER logic for MS–DRG 652, we applied the five criteria as described in section II.D1.b. of the preamble of this proposed rule to determine if it would be appropriate to subdivide cases currently assigned to MS–DRG 652 into severity levels. This analysis includes 2 years of MedPAR claims data to compare the data results from 1 year to the next to avoid making determinations about whether additional severity levels are warranted based on an isolated year's data fluctuation and also, to validate that the established severity levels within a base MS–DRG are supported. Therefore, we reviewed the claims data for base MS–DRG 652 using the September 2018 update of the FY 2018 MedPAR file and the September 2019 update of the FY 2019 MedPAR file, which were used in our analysis of claims data for MS–DRG reclassification requests for FY 2020 and FY 2021. Our findings are shown in the table:

FY Data	Number of Cases	Number of Cases MCC	Number of Cases CC	Number of Cases Non CC	Average Costs No Split	Average Costs MCC	Average Costs CC	Average Costs Non CC	Average Costs MCC/CC combo	Average Costs CC/NonCC combo
2019	11,324	7,567	3,401	356	$25,424	$26,724	$23,085	$20,148	$25,596	$22,806
2018	11,473	7,519	3,490	464	$24,086	$ 25,330	$22,094	$18,931	$24,304	$21,723

We applied the criteria to create subgroups for the three-way severity level split. As discussed in section II.D.1.b., beginning with this FY 2021 IPPS/LTCH PPS proposed rule, we are proposing to expand the previously listed criteria to also include the Non-CC group. We found that the criterion that there be at least a 20% difference in average costs between subgroups failed for the average costs between the MCC and CC subgroups based on the data in both the FY 2018 and FY 2019 MedPAR files. The criterion that there be at least 500 cases for each subgroup also was not met, as shown in the table for both years. Specifically, for the ''with MCC'', ''with CC'', and ''without CC/MCC'' split, there were only 356 cases in the ''without CC/MCC'' subgroup based on the data in the FY 2019 MedPAR file and only 464 cases in the ''without CC/MCC'' subgroup based on the data in the FY 2018 MedPAR file. We then applied the criteria to create subgroups for the two-way severity level splits and found that the criterion that there be at least a 20 percent difference in average costs between the ''with MCC'' subgroup and the ''without MCC'' group failed for both years. The criterion that there be at least a 3-percent reduction in cost variance between the ''with CC/MCC'' and ''without CC/MCC'' subgroups also failed for both years, indicating that the current base MS–DRG 652 maintains the overall accuracy of the IPPS payment system. The claims data do not support a three-way or a two-way severity level split for MS–DRG 652, therefore for FY 2021, we are not proposing to subdivide MS–DRG 652 into severity levels.

As discussed earlier in this section we received two separate but related requests. The second request was that a new MS–DRG be created for kidney transplant cases where the patient received dialysis during the inpatient stay and after the date of the transplant. According to the requestor, transplant hospitals incur higher costs related to post-transplant care of patients who receive kidneys from ''medically complex donors'' (defined by the requestor as coming from organ donors over aged 60 and donors after circulatory death). The requestor also stated that their research indicated that studies consistently identified organ donors over the age of 60 and donors after circulatory death as the most significant areas for growth in increasing the number of organ transplantations, but this growth is hampered by the underutilization of these types of organs. The requestor performed its own data analysis and stated that total standardized costs were 32 percent higher for cases where the beneficiary received dialysis during the inpatient stay and after the date of transplant compared to all other kidney transplant cases currently in MS–DRG 652 (Kidney Transplant), with the additional costs serving as a disincentive to the use of viable kidneys for donation. The requestor asserted that this financially disadvantages transplant centers from using such organs, contributing to the kidney discard rate.

The following ICD–10–PCS procedure codes identify the performance of hemodialysis.

ICD-10-PCS Code	Code Description
5A1D70Z	Performance of urinary filtration, intermittent, less than 6 hours per day
5A1D80Z	Performance of urinary filtration, prolonged intermittent, 6-18 hours per day
5A1D90Z	Performance of urinary filtration, continuous, greater than 18 hours per day

We acknowledge that the request was to review the costs of dialysis performed after kidney transplantation during the same inpatient admission, however our clinical advisors pointed out, that while not routine, it is not uncommon for a patient to require dialysis while admitted for kidney transplantation before the procedure is performed due to factors related to the availability of the organ, nor is it uncommon for a kidney that has been removed from the donor, transported, and then implanted to require dialysis before it returns to optimal function. Therefore, we examined claims data from the September 2019 update of the FY 2019 MedPAR file for all cases in MS–DRG 652 and compared the results to cases representing kidney transplantation with dialysis performed during the same inpatient admission either before or after the date of kidney transplantation. The following table shows our findings:

Kidney Transplant Procedures			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 652 - All cases	11,324	6.0	$25,424
MS-DRG 652 - Cases reporting hemodialysis	3,254	7.6	$30,606

As shown by the table, for MS–DRG 652, we identified a total of 11,324 cases, with an average length of stay of 6.0 days and average costs of $25,424. Of the 11,324 cases in MS–DRG 652, there were 3,254 cases describing the performance of hemodialysis in an admission where the patient received a kidney transplant with an average length of stay of 7.6 days and average costs of $30,606. Our clinical advisors noted that the average length of stay and average costs of cases in MS–DRG 652 describing the performance of hemodialysis in an admission where the patient received a kidney transplant were higher than the average length of stay and average costs for all cases in the same MS–DRG.

In further analyzing this issue, noting that patients can require a simultaneous

pancreas/kidney transplant procedure, we also examined claims data from the September 2019 update of the FY 2019 MedPAR file for all cases in Pre-MDC MS–DRG 008 (Simultaneous Pancreas/Kidney Transplant) and compared the results to cases representing simultaneous pancreas/kidney transplantation with dialysis performed during the same inpatient admission either before or after the date of kidney transplantation. The following table shows our findings:

Pre-MDC MS-DRG 008 Simultaneous Pancreas/Kidney Transplant Procedures			
MS-DRG	**Number of Cases**	**Average Length of Stay**	**Average Costs**
MS-DRG 008 - All cases	374	10.9	$41,926
MS-DRG 008 - Cases reporting hemodialysis	84	13.4	$49,001

As shown by the table, for Pre-MDC MS–DRG 008, we identified a total of 374 cases, with an average length of stay of 10.9 days and average costs of $41,926. Of the 374 cases in Pre-MDC MS–DRG 008, there were 84 cases describing the performance of hemodialysis during an admission where the patient received a simultaneous pancreas/kidney transplant with an average length of stay of 13.4 days and average costs of $49,001. Our clinical advisors again noted that the average length of stay and average costs of cases in Pre-MDC MS–DRG 008 describing the performance of hemodialysis during an admission where the patient received a simultaneous pancreas/kidney transplant were higher than the average length of stay and average costs for all cases in the same Pre-MDC MS–DRG.

Our clinical advisors believe that these hemodialysis procedures either performed before or after kidney transplant or before or after simultaneous pancreas/kidney transplant contribute to increased resource consumption for these transplant patients. While there is not a large number of cases describing a simultaneous pancreas/kidney transplant with hemodialysis procedures either performed before or after transplant represented in the Medicare data, and we generally prefer not to create a new MS–DRG unless it would include a substantial number of cases, we believe creating separate MS–DRGs for these cases would appropriately address the differential in resource consumption consistent with the President's Executive Order on Advancing American Kidney Health (see *https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/*). For these reasons, we are proposing to create new MS–DRGs for the performance of hemodialysis during an admission where the patient received a kidney transplant or simultaneous pancreas/kidney transplant.

To compare and analyze the impact of our suggested modifications, we ran a simulation using the Version 37 ICD–10 MS–DRG GROUPER and the claims data from the September 2019 update of the FY 2019 MedPAR file. The following table reflects our findings for all 3,254 cases representing kidney transplantation with dialysis performed during the same inpatient admission either before or after the date of kidney transplantation with a two-way severity level split.

Proposed New MS-DRGs for Kidney Transplant with Hemodialysis			
MS-DRG	**Number of Cases**	**Average Length of Stay**	**Average Costs**
MS-DRG XXX (Kidney Transplant with Hemodialysis with MCC)	2,195	8.0	$32,360
MS-DRG XXX (Kidney Transplant with Hemodialysis without MCC)	1,059	6.8	$26,972

As shown in the table, there was a total of 2,195 cases for the kidney transplant with hemodialysis with MCC subgroup, with an average length of stay of 8.0 days and average costs of $32,360. There was a total of 1,059 cases for the kidney transplant with hemodialysis without MCC subgroup, with an average length of stay of 6.8 days and average costs of $26,972. We applied the criteria to create subgroups for the two-way severity level split for the proposed MS–DRGs, including our proposed expansion of the criteria to also include the nonCC group, and found that all five criteria were met. For the proposed MS–DRGs, there is (1) at least 500 cases in the MCC subgroup and in the without MCC subgroup; (2) at least 5 percent of the cases are in the MCC subgroup and in the without MCC subgroup; (3) at least a 20 percent difference in average costs between the MCC subgroup and the without MCC subgroup; (4) at least a $2,000 difference in average costs between the MCC subgroup and the without MCC subgroup; and (5) at least a 3-percent reduction in cost variance, indicating that the proposed severity level splits increase the explanatory power of the base MS–DRG in capturing differences in expected cost between the proposed MS–DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the IPPS payment system.

For the cases describing the performance of hemodialysis during an admission where the patient received a simultaneous pancreas/kidney transplant, we identified a total of 84 cases, so the criterion that there are at least 500 or more cases in any subgroup could not be met. Therefore, for FY 2021, we are not proposing to subdivide the proposed new Pre-MDC MS–DRG for the performance of hemodialysis in an admission where the patient received a simultaneous pancreas/kidney transplant into severity levels.

In summary, for FY 2021, taking into consideration that it clinically requires greater resources to perform hemodialysis during an admission where the patient received a kidney or simultaneous pancreas/kidney transplant, we are proposing to create a new Pre-MDC MS–DRG for cases describing the performance of hemodialysis during an admission where the patient received a simultaneous pancreas/kidney transplant. We are also proposing to create two new MS–DRGs with a two-way severity level split for cases describing the performance of hemodialysis in an admission where the patient received a kidney transplant in MDC 11. These proposed new MS–DRGs are proposed new Pre-MDC MS–DRG 019 (Simultaneous Pancreas/Kidney Transplant with Hemodialysis), proposed new MS–DRG 650 (Kidney Transplant with Hemodialysis with MCC) and proposed new MS–DRG 651 (Kidney Transplant with Hemodialysis without MCC). We are proposing to add the procedure codes from current Pre-MDC MS–DRG 008 to the proposed new Pre-MDC MS–DRG 019 with the procedure codes describing a hemodialysis procedure. Similarly, we are also proposing to add the procedure codes from current MS–DRG 652 to the proposed new MS–DRGs 650 and 651 with the procedure codes describing a hemodialysis procedure. We note that the procedure codes describing hemodialysis procedures are designated as non-O.R. procedures, therefore, as part of the logic for these proposed new MS–DRGs, we are also proposing to designate these codes as non-O.R. procedures affecting the MS–DRG.

The diagram illustrates how the proposed MS–DRG logic for Kidney Transplants would function. The diagram (Diagram 1.) begins by asking if the criteria for a Pre-MDC MS–DRG is met. If yes, the logic asks if the criteria for Pre-MDC MS–DRGs 018, 001–006, 014 or 007 is met. If yes, the logic directs the case to either Pre-MDC MS–DRG 018, 001–006, 014 or 007 based on the principal diagnosis and/or procedures reported. If no, the logic asks if there is a simultaneous pancreas/kidney transplant with a qualifying diagnosis reported on the claim. If no, the logic directs the case to either Pre-MDC MS–DRGs 016, 017, or 010–013 based on the principal diagnosis and/or procedures reported. If yes, the logic asks if there was a hemodialysis procedure reported on the claim. If yes, the logic assigns the case to proposed new Pre-MDC MS–DRG 019 (Simultaneous Pancreas/Kidney Transplant with Hemodialysis). If no, the logic assigns the case to existing Pre-MDC MS–DRG 008 (Simultaneous Pancreas/Kidney Transplant).

If the criteria for a Pre-MDC MS–DRG were not met at the first step, the GROUPER logic asks if there was a principal diagnosis of trauma and at least two significant traumas of different body sites. If yes, the logic directs the case to the appropriate MS–DRG in MDC 24 based on the principal diagnosis and procedures reported. If no, the logic asks if there was either a principal diagnosis of HIV infection or a secondary diagnosis of HIV infection with a principal diagnosis of a significant HIV related condition. If yes, the logic directs the case to the appropriate MS–DRG in MDC 25 based on the principal diagnosis and procedures reported. If no, the logic asks if there is kidney transplant procedure reported on the claim. If no, the logic directs the case to the appropriate MDC and MS–DRG based on the principal diagnosis and procedures reported. If yes, the logic asks if there was a hemodialysis procedure reported on the claim. If yes, the logic assigns the case to proposed new MS–DRGs 650 or 651 (Kidney Transplant with Hemodialysis with MCC or without MCC, respectively). If no, the logic assigns the case to existing MS–DRG 652 (Kidney Transplant).

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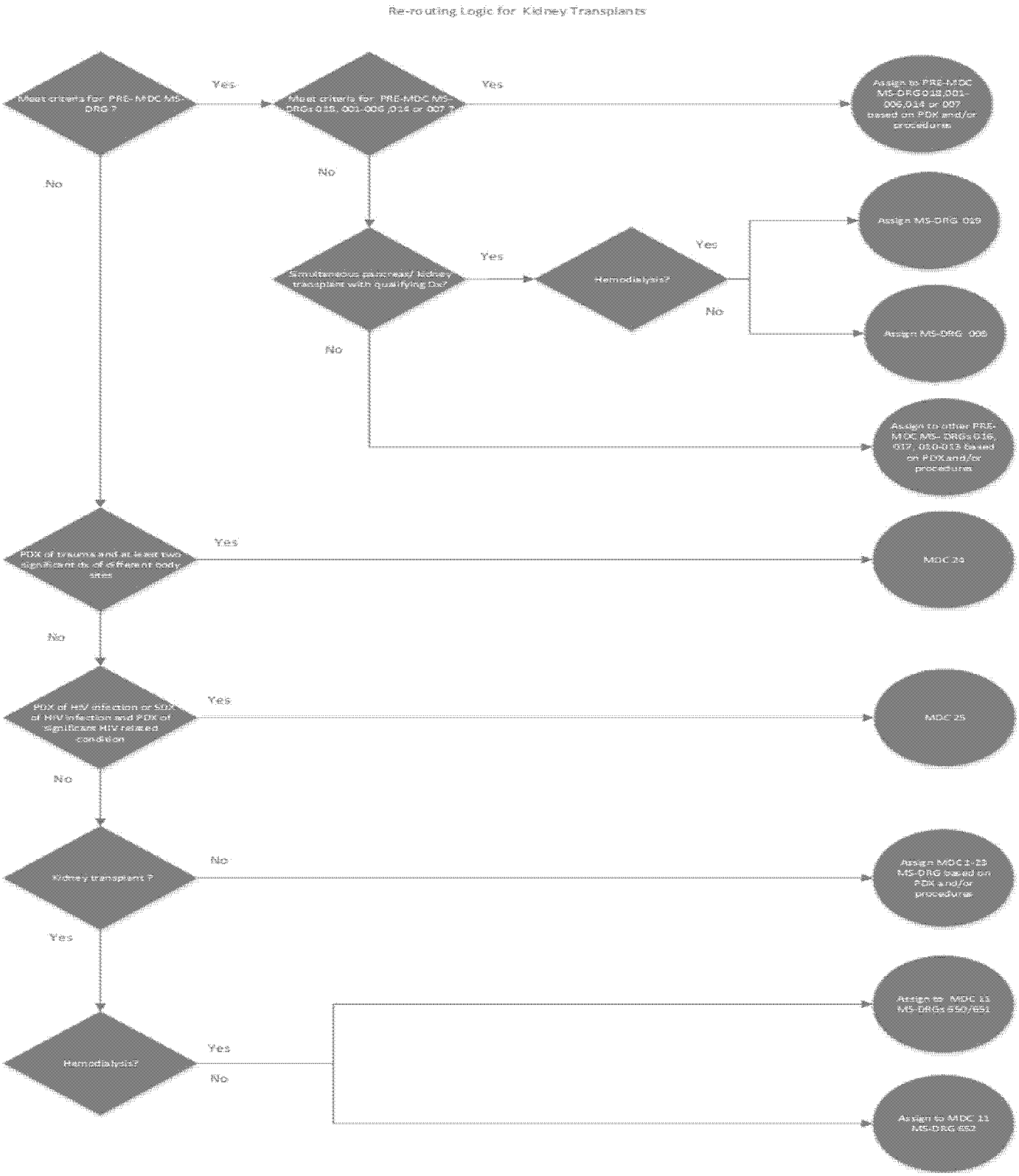
Diagram 1.


Re-routing Logic for Kidney Transplants
Meet criteria for PRE-MDC MS-DRG ?
Yes
Meet criteria for PRE-MDC MS-DRGs 018, 001-005 ,014 or 007 ?
Yes
Assign to PRE-MDC MS-DRG 018,001-005,014 or 007 based on PDX and/or procedures
No
No
Simultaneous pancreas/ kidney transplant with qualifying Dx?
Yes
Hemodialysis?
Yes
No
Assign MS-DRG 029
Assign MS-DRG 005
No
Assign to other PRE-MDC MS- DRGs 016, 017, 010-013 based on PDX and/or procedures
PDX of trauma and at least two significant dx of different body sites
Yes
MDC 24
No
PDX of HIV infection or SDX of HIV infection and PDX of significant HIV related condition
Yes
MDC 25
No
Kidney transplant ?
No
Assign MDC 1-23 MS-DRG based on PDX and/or procedures
Yes
Hemodialysis?
Yes
No
Assign to MDC 11 MS-DRGs 652/651
Assign to MDC 11 MS-DRG 652

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b. Proposed Addition of Diagnoses to Other Kidney and Urinary Tract Procedures Logic

We received a request to add 29 ICD–10–CM diagnosis codes to the list of principal diagnoses assigned to MS–DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract) when reported with procedure codes describing the insertion of totally implantable vascular access devices (TIVADs) and tunneled vascular access devices. The list of 29 ICD–10–CM diagnosis codes submitted by the requestor, as well as their current MDC assignments, are found in the table:

ICD-10-CM Code	Code Description	MDC
T86.11	Kidney transplant rejection	11
T86.12	Kidney transplant failure	11
T86.13	Kidney transplant infection	11
T86.19	Other complication of kidney transplant	11
E10.21	Type 1 diabetes mellitus with diabetic nephropathy	11
E10.22	Type 1 diabetes mellitus with diabetic chronic kidney disease	11
E10.29	Type 1 diabetes mellitus with other diabetic kidney complication	11
E11.21	Type 2 diabetes mellitus with diabetic nephropathy	11
E11.22	Type 2 diabetes mellitus with diabetic chronic kidney disease	11
E11.29	Type 2 diabetes mellitus with other diabetic kidney complication	11
E13.21	Other specified diabetes mellitus with diabetic nephropathy	11
E13.22	Other specified diabetes mellitus with diabetic chronic kidney disease	11
E13.29	Other specified diabetes mellitus with other diabetic kidney complication	11
I13.2	Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease or end stage renal disease	05
T80.211A	Bloodstream infection due to central venous catheter, initial encounter	05
T80.212A	Local infection due to central venous catheter, initial encounter	05
T80.218A	Other infection due to central venous catheter, initial encounter	05
T82.41XA	Breakdown (mechanical) of vascular dialysis catheter	05
T82.42XA	Displacement of vascular dialysis catheter	05
T82.43XA	Leakage of vascular dialysis catheter	05
T82.49XA	Other complication of vascular dialysis catheter	05
T82.7XXA	Infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts, initial encounter	05
T82.818A	Embolism due to vascular prosthetic devices, implants and grafts, initial encounter	05
T82.828A	Fibrosis due to vascular prosthetic devices, implants and grafts, initial encounter	05
T82.838A	Hemorrhage due to vascular prosthetic devices, implants and grafts, initial encounter	05
T82.848A	Pain due to vascular prosthetic devices, implants and grafts, initial encounter	05
T82.858A	Stenosis of other vascular prosthetic devices, implants and grafts, initial encounter	05
T82.868A	Thrombosis due to vascular prosthetic devices, implants and grafts, initial encounter	05
T82.898A	Other specified complication of vascular prosthetic devices, implants and grafts, initial encounter	05

The requestor stated that by adding the codes listed, cases reporting principal diagnosis codes describing complications of dialysis access sites and principal diagnosis codes describing kidney disease in the setting of diabetes or hypertension, would group to MS–DRGs 673, 674, and 675 when a TIVAD or tunneled vascular access device is inserted. The requestor stated that patients who have kidney transplant complications or dialysis catheter complications typically also have chronic kidney disease, end stage renal disease (ESRD) or resolving acute tubular necrosis (ATN) but ICD–10–CM coding guidelines require a complication code to be sequenced first. The requester stated that when reporting a diagnosis code describing ESRD and diabetes, a diabetes code from ICD–10–CM Chapter 4 (Endocrine, Nutritional and Metabolic Diseases) must be sequenced first and when coding ESRD, hypertension, and heart failure, the combination code I13.2 (Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease or end stage renal disease) must be sequenced first per coding guidelines. The requestor pointed out that code I13.11 (Hypertensive heart and chronic kidney disease without heart failure with stage 5 CKD or ESRD) is currently one of the qualifying principal diagnoses in MS–DRGs 673, 674, and 675 when reported with procedure codes describing the insertion of TIVADs or tunneled vascular access devices; therefore, according to the requestor, diagnosis code I13.2 should reasonably be added.

To begin our analysis, we reviewed the GROUPER logic for MS–DRGs 673, 674, and 675 including the special logic in MS–DRGs 673, 674, and 675 for certain MDC 11 diagnoses reported with procedure codes for the insertion of tunneled or totally implantable vascular access devices. As discussed in the FY 2003 IPPS/LTCH PPS final rule (67 FR

49993 through 49994), the procedure code for the insertion of totally implantable vascular access devices was added to the GROUPER logic of DRG 315 (Other Kidney and Urinary Tract O.R. Procedures), the predecessor DRG of MS–DRGs 673, 674, and 675, when combined with principal diagnoses specifically describing renal failure, recognizing that inserting these devices as an inpatient procedure for the purposes of hemodialysis can lead to higher average charges and longer lengths of stay for those cases.

We next reviewed the 29 ICD–10–CM codes submitted by the requestor. Our clinical advisors noted that ICD–10–CM diagnosis codes E10.21, E11.21, and E13.21 describing diabetes mellitus with diabetic nephropathy; codes E10.29, E11.29, and E13.29 describing diabetes mellitus with other diabetic kidney complication; T80.211A, T80.212A, and T80.218A describing infection due to central venous catheters; and codes T82.7XXA, T82.818A, T82.828A, T82.838A, T82.848A, T82.858A, T82.868A, and T82.898A describing complications of cardiac and vascular prosthetic devices, implants and grafts, are not necessarily indicative of a patient having renal (kidney) failure requiring the insertion of a TIVAD or a tunneled vascular access device to allow access to the patient's blood for hemodialysis purposes. TIVADs and tunneled vascular access devices are widely used to provide central venous access for the administration of intravenous antibiotics, chemotherapeutic agents, parenteral nutrition and other treatments. They are used in a variety of disease groups, and in both children and adults. As such, our clinical advisors do not support adding these diagnoses to the list of principal diagnosis codes in MS–DRG 673, 674, and 675 when reported with procedure codes describing the insertion of TIVADs and tunneled vascular access devices. They noted that TIVADs and tunneled vascular access devices may be inserted for a variety of principal diagnoses, and that adding these 17 diagnoses that are not specific to renal failure would not maintain the clinical coherence with other cases in this subset of cases in MS–DRGs 673, 674, and 675.

Our clinical advisors also do not support adding ICD–10–CM diagnosis code I13.2 (Hypertensive heart and chronic kidney disease with heart failure and with stage 5 chronic kidney disease, or end stage renal disease) to the special logic in MS–DRGs 673, 674, and 675. As discussed previously, code I13.2 is assigned to MDC 05 (Diseases and Disorders of the Circulatory System). Our clinical advisors agreed it would not be appropriate to move this diagnosis into MDC 11 because it would inadvertently cause cases reporting this same MDC 05 diagnosis with circulatory system procedures to be assigned to an unrelated MS–DRG.

Therefore, for the reasons described previously, we are not proposing to add the following 18 ICD–10–CM codes to the list of principal diagnosis codes for MS–DRGs 673, 674, and 675 when reported with a procedures code describing the insertion of a TIVAD or a tunneled vascular access device: E10.21, E10.29, E11.21, E11.29, E13.21, E13.29, I13.2, T80.211A, T80.212A, T80.218A, T82.7XXA, T82.818A, T82.828A, T82.838A, T82.848A, T82.858A, T82.868A, and T82.898A.

We then reviewed the remaining 11 diagnosis codes submitted by the requestor. Codes T82.41XA, T82.42XA, T82.43XA and T82.49XA describe mechanical complications of vascular dialysis catheters. Our clinical advisors believe the insertion of TIVADs or tunneled vascular access devices for the purposes of hemodialysis is clearly clinically related to diagnosis codes describing a mechanical complication of a vascular dialysis catheter and that for clinical coherence, these cases should be grouped with the subset of cases that report the insertion of totally implantable vascular access devices or tunneled vascular access devices as an inpatient procedure for the purposes of hemodialysis for renal failure.

Codes T82.41XA, T82.42XA, T82.43XA and T82.49XA that describe mechanical complications of vascular dialysis catheters are currently assigned to MDC 05 and would require reassignment to MDC 11 in MS–DRGs 673, 674, and 675 to group with the subset of cases that report the insertion of totally implantable vascular access devices or tunneled vascular access devices as an inpatient procedure for the purposes of hemodialysis for renal failure. We examined claims data from the September 2019 update of the FY 2019 MedPAR file for all cases reporting procedures describing the insertion of TIVADs or tunneled vascular access devices with a principal diagnosis from the T82.4- series in MDC 05 and compared this data to cases in MS–DRGs 673, 674 and 675. The following table shows our findings:

MS-DRGs 673, 674 and 675 Compared To Cases Reporting Procedures Describing The Insertion of TIVADs or Tunneled Vascular Access Devices With A Principal Diagnosis Code From T82.4- Series In MDC 05			
MS-DRG	**Number of Cases**	**Average Length of Stay**	**Average Costs**
MS-DRG 673 - All cases	13,068	11.0	$26,528
Cases reporting procedures describing the insertion of TIVADs or tunneled vascular access devices with a principal diagnosis from T82.4- series in MDC 05 with secondary diagnosis designated as MCC	1,025	4.6	$14,882
MS-DRG 674 - All cases	6,592	7.6	$17,491
Cases reporting procedures describing the insertion of TIVADs or tunneled vascular access devices with a principal diagnosis from T82.4- series in MDC 05 with secondary diagnosis designated as CC	2	6.0	$15,016
MS-DRG 675 - All cases	437	3.4	$12,506
Cases reporting procedures describing the insertion of TIVADs or tunneled vascular access devices with a principal diagnosis from T82.4- series in MDC 05 without secondary diagnosis designated as CC or MCC	1	3.0	$9,317

As shown in the table, there were 13,068 cases in MS–DRG 673 with an average length of stay of 11 days and average costs of $26,528. There were 1,025 cases reporting a principal diagnosis describing a mechanical complication of vascular dialysis catheter, with a secondary diagnosis of MCC, and a procedure code for the insertion of a TIVAD or tunneled vascular access device with an average length of stay of 4.6 days and average costs of $14,882. There were 6,592 cases in MS–DRG 674 with an average length of stay of 7.6 days and average costs of $17,491. There were 2 cases reporting a principal diagnosis describing a mechanical complication of vascular dialysis catheter, with a secondary diagnosis of CC, and a procedure code for the insertion of a TIVAD or tunneled vascular access device with an average length of stay of 6 days and average costs of $15,016. There were 437 cases in MS–DRG 675 with an average length of stay of 3.4 days and average costs of $12,506. There was one case reporting a principal diagnosis describing a mechanical complication of vascular dialysis catheter, without a secondary diagnosis of CC or MCC, and a procedure code for the insertion of a TIVAD or tunneled vascular access device with a length of stay of 3 days and costs of $9,317. Our clinical advisors noted that the average length of stay and average costs of cases reporting a diagnosis describing a mechanical complication of a vascular dialysis catheter and the insertion of a TIVAD or a tunneled vascular access device are lower than for all cases in MS–DRGs 673, 674, and 675, respectively.

For the reasons discussed, our clinical advisors believe that it is clinically appropriate for the four ICD–10–CM diagnosis codes describing a mechanical complication of a vascular dialysis catheter to group to the subset of GROUPER logic that recognizes the insertion of totally implantable vascular access devices or tunneled vascular access devices as an inpatient procedure for the purposes of hemodialysis. Therefore, we are proposing to reassign ICD–10–CM diagnosis codes T82.41XA, T82.42XA, T82.43XA, and T82.49XA from MDC 05 in MS–DRGs 314, 315, and 316 (Other Circulatory System Diagnoses with MCC, with CC, and without CC/MCC, respectively) to MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract) assigned to MS–DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC, and without CC/MCC, respectively) and 698, 699, and 700 (Other Kidney and Urinary Tract Diagnoses with MCC, with CC, and without CC/MCC, respectively).

In reviewing ICD–10–CM codes E10.22, E11.22, and E13.22 describing diabetes mellitus with diabetic chronic kidney disease, we noted that related ICD–10–CM diagnosis code E09.22 (Drug or chemical induced diabetes mellitus with diabetic chronic kidney disease) is also not included in the current list of diagnosis codes included in the special logic in MS–DRGs 673, 674, and 675 for certain MDC 11 diagnoses reported with procedure codes for the insertion of tunneled or totally implantable vascular access devices, and therefore we included E09.22 in our review. ICD–10–CM assumes a causal relationship between diabetes mellitus and chronic kidney disease. According to the ICD–10–CM Official Guidelines for Coding and Reporting, the word ''with'' or ''in'' should be interpreted to mean ''associated with'' or ''due to'' when it appears in a code title, the Alphabetic Index (either under a main term or subterm), or an instructional note in the Tabular List, meaning these conditions should be coded as related even in the absence of provider documentation explicitly linking them, unless the documentation clearly states the conditions are unrelated. To code diabetic chronic kidney disease in ICD–10–CM, instructional notes direct to ''code first any associated diabetic chronic kidney disease'' (that is, E09.22, E10.22, E11.22, and E13.22) with a second code from subcategory of N18

listed after the diabetes code to specify the stage of chronic kidney disease. Recognizing that coding guidelines instruct to code E09.22, E10.22, E11.22, and E13.22 before codes that specify the stage of chronic kidney disease, our clinical advisors recommend adding diabetic codes E09.22, E10.22, E11.22, and E13.22 when reported with a secondary diagnosis of either N18.5 Chronic kidney disease, stage 5) or N18.6 (End stage renal disease) to the special logic in MS–DRGs 673, 674, and 675 since these diagnosis code combinations describe an indication that could require the insertion of a totally implantable vascular access device or a tunneled vascular access device to allow access to the patient's blood for hemodialysis purposes.

ICD–10–CM codes T86.11, T86.12, T86.13, and T86.19 describe complications of kidney transplant and are currently assigned to MDC 11. Our clinical advisors believe these diagnoses are also indications for hemodialysis and these cases represent a distinct, recognizable clinical group similar to those cases in the subset of cases assigned to the special logic in MS–DRGs 673, 674, and 675 when reported with procedure codes describing the insertion of totally implantable vascular access devices or tunneled vascular access devices for hemodialysis.

In summary, we are proposing to add ICD–10–CM codes E09.22, E10.22, E11.22, and E13.22, when reported with a secondary diagnosis of N18.5 or N18.6, to the list of principal diagnosis codes in the subset of GROUPER logic in MS–DRGs 673, 674, and 675 that recognizes the insertion of totally implantable vascular access devices or tunneled vascular access devices as an inpatient procedure for the purposes of hemodialysis. We are also proposing to add ICD–10–CM codes T86.11, T86.12, T86.13, and T86.19 to the list of principal diagnosis codes in this subset of GROUPER logic in MS–DRGs 673, 674, and 675.

Lastly, we reviewed the current list of 20 MDC 11 diagnoses assigned to the special logic in MS–DRGs 673, 674, and 675 when reported with procedure codes for the insertion of tunneled or totally implantable vascular access devices. The list of MDC 11 diagnosis codes currently included in the special logic of MS–DRGs 673, 674, and 675 are found in the following table:

ICD-10-CM Code	Code Description
E88.3	Tumor lysis syndrome
I12.0	Hypertensive chronic kidney disease with stage 5 chronic kidney disease or end stage renal disease
I12.9	Hypertensive chronic kidney disease with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.10	Hypertensive heart and chronic kidney disease without heart failure, with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease
I13.11	Hypertensive heart and chronic kidney disease without heart failure, with stage 5 chronic kidney disease, or end stage renal disease
N17.0	Acute kidney failure with tubular necrosis
N17.1	Acute kidney failure with acute cortical necrosis
N17.2	Acute kidney failure with medullary necrosis
N17.8	Other acute kidney failure
N17.9	Acute kidney failure, unspecified
N18.1	Chronic kidney disease, stage 1
N18.2	Chronic kidney disease, stage 2 (mild)
N18.3	Chronic kidney disease, stage 3 (moderate)
N18.4	Chronic kidney disease, stage 4 (severe)
N18.5	Chronic kidney disease, stage 5
N18.6	End stage renal disease
N18.9	Chronic kidney disease, unspecified
N19	Unspecified kidney failure
R34	Anuria and oliguria
T79.5XXA	Traumatic anuria, initial encounter

Our clinical advisors pointed out that ICD–10–CM codes I12.9, I13.10, N18.1, N18.2, N18.3, N18.4, and N18.9 do not describe renal failure and they do not describe indications that would generally require the insertion of totally implantable vascular access devices or tunneled vascular access devices for the purposes of hemodialysis. Our advisors

note hemodialysis replicates the function of the kidneys. In cases of acute kidney failure and anuria, hemodialysis is indicated to prevent urea and other waste material from building up in the blood until the kidneys return to normal function. A diagnosis of chronic kidney disease stages 1 through 4, however, means the kidneys still have the ability to filter waste and extra fluid out of the blood. Dialysis is not often not initiated in chronic kidney disease until the chronic kidney disease progresses to stage 5 or ESRD, which is defined as when kidney function drops to 15 percent or less. Our clinical advisors stated that these seven codes do not describe indications requiring the insertion of totally implantable vascular access devices or tunneled vascular access devices for hemodialysis and recommended these codes be removed from the special logic in MS–DRGs 673, 674, and 675.

We examined claims data from the September 2019 update of the FY 2019 MedPAR file for MS—DRGs 673, 674, and 675 for this subset of cases to determine if there were any cases that reported one of the seven ICD–10–CM codes in the special logic of MS–DRGs 673, 674, and 675 that do not necessarily describe indications requiring the insertion of totally implantable vascular access devices or tunneled vascular access devices for hemodialysis, the frequency with which they were reported and the relative resource use as compared with all cases assigned to the special logic in MS–DRGs 673, 674, and 675. The following table shows our findings:

MS-DRG 673, 674 and 675				
MS-DRG	**Description**	**Number of Cases**	**Average Length of Stay**	**Average Costs**
673	MDC 11 diagnosis with procedure code describing insertion of TIVAD/tunneled VAD	7,391	12.1	$28,273
	Cases with principal diagnosis of I12.9, I13.10, N18.1, N18.2, N18.3, N18.4, or N18.9 with procedure code describing insertion of TIVAD/tunneled VAD	34	14.2	$27,844
674	MDC 11 diagnosis with procedure code describing insertion of TIVAD/tunneled VAD	3,055	7.8	$17,107
	Cases with principal diagnosis of I12.9, I13.10, N18.1, N18.2, N18.3, N18.4, or N18.9 with procedure code describing insertion of TIVAD/tunneled VAD	30	7.2	$11,227
675	MDC 11 diagnosis with procedure code describing insertion of TIVAD/tunneled VAD	58	6.1	$12,582
	Cases with principal diagnosis of I12.9, I13.10, N18.1, N18.2, N18.3, N18.4, of N18.9 with procedure code describing insertion of TIVAD/tunneled VAD	1	4	$6,549

As shown by the table, for MS–DRG 673, we identified a total of 7,391 cases assigned to the special logic within this MS–DRG with an average length of stay of 12.1 days and average costs of $28,273. Of these 7,391 cases in the subset of MS–DRG 673, there were 34 cases describing insertion of a TIVAD or tunneled vascular access device with a principal diagnosis of I12.9, I13.10, N18.1, N18.2, N18.3, N18.4, or N18.9 with an average length of stay of 14.2 days and average costs of $27,844. For MS–DRG 674, we identified a total of 3,055 cases assigned to the special logic within this MS–DRG with an average length of stay of 7.8 days and average costs of $17,107. Of these 3,055 cases in the subset of MS–DRG 674, there were 30 cases describing insertion of a TIVAD or tunneled vascular access device with a principal diagnosis of I12.9, I13.10, N18.1, N18.2, N18.3, N18.4, or N18.9 with an average length of stay of 7.2 days and average costs of $11,227. For MS–DRG 675, we identified a total of 58 cases assigned to the special logic within this MS–DRG with an average length of stay of 6.1 days and average costs of $12,582. Of these 58 cases in the subset of MS–DRG 675, there was one case describing insertion of a TIVAD or tunneled vascular access device with a principal diagnosis of I12.9, I13.10, N18.1, N18.2, N18.3, N18.4, or N18.9 with a length of stay of 4 days and costs of $6,549. Overall, for MS–DRGs 673, 674 and 675, there were a relatively small number of cases reporting a principal diagnosis of I12.9, I13.10, N18.1, N18.2, N18.3, N18.4, or N18.9 and a procedure code describing the insertion of a TIVAD or tunneled vascular access device demonstrating

that these conditions are not typically addressed by insertion of these devices.

As stated previously, TIVADs and tunneled vascular access devices may be inserted for a variety of principal diagnoses. Our clinical advisors believe that continuing to include these seven diagnoses that are not specific to renal failure or that do not otherwise describe indications requiring the insertion of totally implantable vascular access devices or tunneled vascular access devices for hemodialysis would not maintain clinical coherence with other cases in this subset of cases in MS–DRGs 673, 674, and 675. Therefore, for the reasons stated, we are proposing to remove ICD–10–CM codes I12.9, I13.10, N18.1, N18.2, N18.3, N18.4, and N18.9 from the subset of GROUPER logic in MS–DRGs 673, 674, and 675 that recognizes the insertion of totally implantable vascular access devices or tunneled vascular access devices as an inpatient procedure for the purposes of hemodialysis.

9. MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms): Inferior Vena Cava Filter Procedures

We received a request to review the GROUPER logic in MDC 17. The requester stated that cases reporting the introduction of a high dose chemotherapy agent, or reporting a chemotherapy principal diagnosis with a secondary diagnosis describing acute leukemia, are assigned to medical MS–DRGs 837 (Chemotherapy with Acute Leukemia as Secondary Diagnosis or with High Dose Chemotherapy Agent with MCC), MS–DRG 838 (Chemotherapy with Acute Leukemia as Secondary Diagnosis with CC or High Dose Chemotherapy Agent), and MS–DRG 839 (Chemotherapy with Acute Leukemia as Secondary Diagnosis without CC/MCC). However, when procedure codes describing the placement of an inferior vena cava (IVC) filter, namely 06H03DZ (Insertion of intraluminal device into inferior vena cava, percutaneous approach), are also reported with the same codes describing the introduction of a high dose chemotherapy agent or report a chemotherapy principal diagnosis with a secondary diagnosis describing acute leukemia, the cases are assigned to surgical MS–DRGs 829 and 830 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other Procedure with and without CC/MCC, respectively). According to the requestor, the additional resources used by the hospital to place an IVC filter should not result in assignment to lower-weighted MS–DRGs.

The ICD–10–PCS codes that describe the insertion of an infusion device or the insertion of an intraluminal device into the inferior vena cava are listed in the following table.

ICD-10-PCS Code	Code Description
06H003T	Insertion of infusion device, via umbilical vein, into inferior vena cava, open approach
06H003Z	Insertion of infusion device, into inferior vena cava, open approach
06H00DZ	Insertion of intraluminal device, into inferior vena cava, open approach
06H033T	Insertion of infusion device, via umbilical vein, into inferior vena cava, percutaneous approach
06H033Z	Insertion of infusion device, into inferior vena cava, percutaneous approach
06H03DZ	Insertion of intraluminal device, into inferior vena cava, percutaneous approach
06H043Z	Insertion of infusion device, into inferior vena cava, percutaneous endoscopic approach
06H04DZ	Insertion of intraluminal device, into inferior vena cava, percutaneous endoscopic approach

Our analysis of this grouping issue confirmed that, when procedure code 06H03DZ (Insertion of intraluminal device into inferior vena cava, percutaneous approach) is reported with a procedure code describing the introduction of a high dose chemotherapy agent, or when it is reported with a chemotherapy principal diagnosis code with a secondary diagnosis code describing acute leukemia, these cases group to surgical MS–DRGs 829 and 830. ICD–10–PCS procedure code 06H03DZ identifies the placement of an IVC filter and is designated as an extensive O.R. procedure for purposes of MS–DRG assignment. We then examined the GROUPER logic for medical MS–DRGs 837, 838 and 839. The GROUPER logic for MS–DRGs 837, 838, and 839 is defined by a principal diagnosis of chemotherapy identified with ICD–10–CM diagnosis codes Z08 (Encounter for follow-up examination after completed treatment for malignant neoplasm), Z51.11 (Encounter for antineoplastic chemotherapy) or Z51.112 (Encounter for antineoplastic immunotherapy) along with a secondary diagnosis of acute leukemia or a procedure code for the introduction of a high dose chemotherapy agent as reflected in the logic table:

Secondary Diagnosis of Acute Leukemia	High Dose Chemotherapy Agent	MCC	CC	MS-DRG
Yes		Yes	n/a	837 (Chemotherapy with Acute Leukemia as Secondary Diagnosis or with High Dose Chemotherapy Agent with MCC)
No	Yes	Yes	n/a	837 (Chemotherapy with Acute Leukemia as Secondary Diagnosis or with High Dose Chemotherapy Agent with MCC)
Yes	No	No	Yes	838 (Chemotherapy with Acute Leukemia as Secondary Diagnosis with CC or High Dose Chemotherapy Agent)
No	Yes	No	n/a	838 (Chemotherapy with Acute Leukemia as Secondary Diagnosis with CC or High Dose Chemotherapy Agent)
Yes	No	No	No	839 (Chemotherapy with Acute Leukemia as Secondary Diagnosis without CC/MCC)

We refer the reader to the ICD–10 MS–DRG Version 37 Definitions Manual (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for the listed MS–DRGs.

We examined claims data from the September 2019 update of the FY 2019 MedPAR file for all cases in MS–DRGs 829 and 830 and for cases reporting the insertion of an IVC filter (procedure codes 06H00DZ, 06H03DZ, and 06H04DZ) with a procedure code describing the introduction of a high dose chemotherapy agent, or with a chemotherapy principal diagnosis code with a secondary diagnosis code describing acute leukemia. Our findings are shown in the following table.

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
829	All cases	1,697	9.2	$24,188
	Cases reporting insertion of an IVC filter procedure code with the introduction of a high dose chemotherapy agent, or with a chemotherapy principal diagnosis code with a secondary diagnosis code describing acute leukemia	18	25.6	$83,861
830	All cases	311	2.9	$10,885

As shown in the table, there were a total of 1,697 cases with an average length of stay of 9.2 days and average costs of $24,188 in MS–DRG 829. Of those 1,697 cases, there were 18 cases reporting procedure code 06H03DZ with a procedure code describing the introduction of a high dose chemotherapy agent, or with a chemotherapy principal diagnosis code with a secondary diagnosis code describing acute leukemia with an average length of stay of 25.6 days and average costs of $83,861. We note that there were no cases reporting procedure codes 06H00DZ or 06H04DZ. For MS–DRG 830, there were a total of 311 cases with an average length of stay of 2.9 days and average costs of $10,885. We found zero cases in MS–DRG 830 reporting a procedure code for the insertion of an IVC filter with a procedure code describing the introduction of a high dose chemotherapy agent, or with a chemotherapy principal diagnosis code with a secondary diagnosis code describing acute leukemia. Based on the claims data, the cases reporting procedure code 06H03DZ with a procedure code describing the introduction of a high dose chemotherapy agent, or with a chemotherapy principal diagnosis code with a secondary diagnosis code describing acute leukemia have higher average costs ($83,861 versus $24,188) and a longer average length of stay (25.6

days versus 9.2 days) than all the cases in MS–DRG 829.

We also reviewed the claims data for MS–DRGs 837, 838, and 839. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
837 - All cases	1,776	17	$40,667
838 - All cases	1,172	7.3	$16,594
839 - All cases	810	5	$10,994

As shown in the table, there were a total of 1,776 cases with an average length of stay of 17 days and average costs of $40,667 in MS–DRG 837. There were a total of 1,172 cases with an average length of stay of 7.3 days and average costs of $16,594 in MS–DRG 838. There were a total of 810 cases with an average length of stay of 5 days and average costs of $10,994 in MS–DRG 839. Based on the claims data, the cases reporting procedure code 06H03DZ with a procedure code describing the introduction of a high dose chemotherapy agent, or with a chemotherapy principal diagnosis code with a secondary diagnosis code describing acute leukemia again have higher average costs ($83,861 versus $40,667, $16,594, and $10,994 respectively) and a longer average length of stay (25.6 days versus 17 days, 7.3 days and 5 days, respectively) than all the cases in MS–DRG 837, 838, and 839. Our clinical advisors reviewed the claims data and noted there were only a small number of cases reporting procedure code 06H03DZ with a procedure code describing the introduction of a high dose chemotherapy agent, or with a chemotherapy principal diagnosis code with a secondary diagnosis code describing acute leukemia, and believe there may have been other factors contributing to the higher costs for these cases. Our clinical advisors stated the procedure to insert an IVC filter is not surgical in nature and recommended further analysis.

We performed further analysis on the other ICD–10–PCS codes describing the insertion of a device into the inferior vena cava to identify if they have a similar extensive O.R. designations and noted inconsistencies among the O.R. and non-O.R. designations. In Version 37 of the ICD–10 MS–DRGs, ICD–10–PCS procedure codes 06H003T, 06H003Z, 06H033T, 06H033Z, and 06H043Z identify the insertion of an infusion device into the inferior vena cava with various approaches and are classified as Non-O.R. procedures. ICD–10–PCS procedure codes 06H00DZ, 06H03DZ, and 06H04DZ identify the insertion of an intraluminal device into the inferior vena cava (IVC filter procedure) with various approaches and are classified as extensive O.R. procedures. Our clinical advisors indicated that codes 06H00DZ, 06H03DZ, and 06H04DZ describing the insertion of an intraluminal device into the inferior vena cava do not require the resources of an operating room, that the procedure to insert an IVC filter is not surgical in nature and that these procedures are comparable to the related ICD–10–PCS procedure codes that describe the insertion of infusion devices into the inferior vena cava that are currently designated as Non-O.R. procedures. Our clinical advisors believe that, given the similarity in factors such as complexity, resource utilization, and lack of a requirement for anesthesia administration between all procedures describing insertion of a device into the inferior vena cava, it would be more appropriate to designate these three ICD–10–PCS codes describing the insertion of an intraluminal device into the inferior vena cava as Non-O.R. procedures. Therefore, we are proposing to remove ICD–10–PCS procedure codes 06H00DZ, 06H03DZ, and 06H04DZ from the FY 2021 ICD–10 MS–DRG Version 38 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures. Under this proposal, these procedures would no longer impact MS–DRG assignment.

10. Review of Procedure Codes in MS–DRGs 981 Through 983 and 987 Through 989

We annually conduct a review of procedures producing assignment to MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 987 through 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) on the basis of volume, by procedure, to see if it would be appropriate to move cases reporting these procedure codes out of these MS–DRGs into one of the surgical MS–DRGs for the MDC into which the principal diagnosis falls. The data are arrayed in two ways for comparison purposes. We look at a frequency count of each major operative procedure code. We also compare procedures across MDCs by volume of procedure codes within each MDC. We use this information to determine which procedure codes and diagnosis codes to examine.

We identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical MS–DRGs for the MDC in which the diagnosis falls. We also consider whether it would be more appropriate to move the principal diagnosis codes into the MDC to which the procedure is currently assigned.

In addition to this internal review, we also consider requests that we receive to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989 to determine if it would be appropriate to add procedure codes to one of the surgical MS DRGs for the MDC into which the principal diagnosis falls or to move the principal diagnosis to the surgical MS DRGs to which the procedure codes are assigned.

Based on the results of our review of the claims data from the September 2019 update of the FY 2019 MedPAR file, as well as our review of the requests that we received to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989, we are proposing to move the cases reporting the procedures and/or principal diagnosis codes described in this section of this rule from MS–DRGs 981 through 983 or MS–DRGs 987 through 989 into one of the surgical MS–DRGs for the MDC into which the principal diagnosis or procedure is assigned.

a. Horseshoe Abscess With Drainage

We received a request to reassign cases reporting a principal diagnosis of a horseshoe abscess with a procedure involving open drainage of perineum subcutaneous tissue and fascia from MS–DRGs 987, 988, and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 356, 357, and 358 (Other Digestive System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 06. ICD–10–CM diagnosis code K61.31 (Horseshoe abscess) is used to report a horseshoe abscess and is currently assigned to MDC 06 (Diseases and Disorders of the Digestive System). A horseshoe abscess is a specific type of ischiorectal abscess caused by an abscessed anal gland located in the posterior midline of the anal canal with suppuration found in the ischiorectal fossae. ICD–10–PCS procedure code 0J9B0ZZ (Drainage of perineum subcutaneous tissue and fascia, open approach) may be reported to describe drainage of an abscess in the ischiorectal space and is currently assigned to MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue), MDC 09 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast), MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs) and MDC 24 (Multiple Significant Trauma).

Our analysis of this grouping issue confirmed that, when a horseshoe abscess is reported as a principal diagnosis with ICD–10–PCS procedure code 0J9B0ZZ, these cases group to MS–DRGs 987, 988, and 989. As previously noted, whenever there is a surgical procedure reported on the claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in an MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures''.

We examined the claims data to identify cases reporting procedure code 0J9B0ZZ with a principal diagnosis of K61.31 that are currently grouping to MS–DRGs 987, 988, and 989. Our findings are shown in this table:

MS-DRGs 987 – 989: Cases Reporting Procedure Describing Open Drainage Of Perineum Subcutaneous Tissue And Fascia with Principal Diagnosis K61.31

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
987	1	5	$10,966
988	0	0	$0
989	2	1.5	$3,596

As previously noted, the requestor asked that we reassign these cases to MS–DRGs 356, 357, and 358. We therefore examined the data for all cases in MS–DRGs 356, 357, and 358. Our findings are shown in this table:

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
356 – All cases	7,525	10.4	$30,071
357 – All cases	5,759	5.9	$16,452
358 – All cases	1,191	3.4	$10,031

While our clinical advisors noted that the average length of stay and average costs of cases in MS–DRGs 356, 357, and 358 are higher than the average length of stay and average costs for the small subset of cases reporting procedure code 0J9B0ZZ and a principal diagnosis code of K61.31 in MS–DRGs 987, 988, and 989, they believe that the procedure is clearly clinically related to the principal diagnosis and is a logical accompaniment of the diagnosis. Therefore, they believe it is clinically appropriate for the procedure to group to the same MS–DRGs as the principal diagnosis.

Therefore, we are proposing to add ICD–10–PCS procedure code 0J9B0ZZ to MDC 06 in MS–DRGs 356, 357, and 358. Under this proposal, cases reporting procedure code 0J9B0ZZ in conjunction with a principal diagnosis from MDC 06, such as diagnosis code K61.31, would group to MS–DRGs 356, 357, and 358.

b. Chest Wall Deformity With Supplementation

We received a request to reassign cases reporting a principal diagnosis of acquired deformity of chest and rib with a procedure involving the placement of a biological or synthetic material that supports or strengthens the body part from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures, with MCC, with CC, and without CC/MCC, respectively) in MDC 08.

ICD–10–CM diagnosis code M95.4 (Acquired deformity of chest and rib) is used to report this condition and is currently assigned to MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue). ICD–10–PCS procedure codes 0WU807Z (Supplement chest wall with autologous tissue substitute, open approach), 0WU80JZ (Supplement chest wall with synthetic substitute, open approach)

and 0WU80KZ (Supplement chest wall with nonautologous tissue substitute, open approach) may be reported to describe procedures to supplement or reinforce the chest wall with biologic or synthetic material. ICD–10–PCS procedure codes 0WU807Z and 0WU80KZ are currently assigned to MDC 04 (Diseases and Disorders of the Respiratory System). We note that ICD–10–PCS procedure code 0WU80JZ is already assigned to MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) as well as MDC 04 (Diseases and Disorders of the Respiratory System), so these cases already group to MS–DRGs 515, 516, and 517 when reported with a principal diagnosis of ICD–10–CM diagnosis code M95.4.

Our analysis of this grouping issue confirmed that when diagnosis code M95.4 is reported as a principal diagnosis with ICD–10–PCS procedure codes 0WU807Z or 0WU80KZ, these cases group to MS–DRGs 981, 982, and 983. As noted in the previous discussion, whenever there is a surgical procedure reported on the claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in an MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures''.

We examined the claims data to identify cases reporting procedure codes 0WU807Z or 0WU80KZ with principal diagnosis code M95.4 that are currently grouping to MS–DRGs 981, 982, and 983. Our analysis showed one case reporting a principal diagnosis of code M95.4 with procedure code 0WU807Z, with a length of stay of 2.0 days and average costs of $11,594 in MS–DRG 983. We found zero cases in MS–DRGs 981 and 982 reporting procedure codes 0WU807Z or 0WU80KZ and a principal diagnosis of M95.4.

We also examined the data for cases in MS–DRGs 515, 516, and 517, and our findings are shown in this table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
515 – All cases	4,655	8.2	$22,176
516 – All cases	13,308	4.6	$14,225
517 – All cases	11,992	2.6	$10,318

While there is only one case reporting procedure codes 0WU807Z or 0WU80KZ with principal diagnosis M95.4 in MS–DRGs 981, 982, and 983, our clinical advisors reviewed this request and believe that the cases involving procedures of chest wall supplementation with a principal diagnosis of acquired deformity of chest and rib represent a distinct, recognizable clinical group similar to those cases in MS–DRGs 515, 516, and 517, and that procedures reporting 0WU80JZ and 0WU80KZ are clearly related to the principal diagnosis code. They believe that it is clinically appropriate for the three ICD–10–PCS codes describing procedures to supplement or reinforce the chest wall with biologic or synthetic material to group to the same MS–DRGs as the principal diagnoses.

Therefore, we are proposing to add ICD–10–PCS procedure codes 0WU807Z and 0WU80KZ to MDC 08 in MS–DRGs 515, 516, and 517. Under this proposal, cases reporting procedure codes 0WU807Z or 0WU80KZ in conjunction with a principal diagnosis code from MDC 08 would group to MS–DRGs 515, 516, and 517.

c. Hepatic Malignancy With Hepatic Artery Embolization

We received a request to reassign cases for hepatic malignancy when reported with procedures involving the embolization of a hepatic artery from MS–DRGs 987, 988, and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 423, 424, and 425 (Other Hepatobiliary or Pancreas Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 08.

ICD–10–PCS procedure code 04V33DZ (Restriction of hepatic artery with intraluminal device, percutaneous approach) may be reported to describe embolization procedures to narrow or partially occlude a hepatic artery with an intraluminal device and is currently assigned to MDC 05 (Diseases and Disorders of the Circulatory System). ICD–10–PCS procedure code 04L33DZ (Occlusion of hepatic artery with intraluminal device, percutaneous approach) may be reported to describe embolization procedures to completely close off a hepatic artery with an intraluminal device and is currently assigned to MDC 05 (Diseases and Disorders of the Circulatory System) and MDC 06 (Diseases and Disorders of the Digestive System).

The requestor did not provide an ICD–10–CM diagnosis code in its request so we reviewed ICD–10–CM diagnosis codes in the C00 through D49 code range to identify conditions that describe hepatic malignancies. We identified the following fourteen ICD–10–CM diagnosis codes, all currently assigned to MDC 07 (Diseases and Disorders of the Hepatobiliary System & Pancreas):

ICD-10-CM Code	Code Description
C22.0	Liver cell carcinoma
C22.1	Intrahepatic bile duct carcinoma
C22.2	Hepatoblastoma
C22.3	Angiosarcoma of liver
C22.4	Other sarcomas of liver
C22.7	Other specified carcinomas of liver
C22.8	Malignant neoplasm of liver, primary, unspecified as to type
C22.9	Malignant neoplasm of liver, not specified as primary or secondary
C24.0	Malignant neoplasm of extrahepatic bile duct
C24.8	Malignant neoplasm of overlapping sites of biliary tract
C24.9	Malignant neoplasm of biliary tract, unspecified
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
C7B.02	Secondary carcinoid tumors of liver
D01.5	Carcinoma in situ of liver, gallbladder and bile ducts

Our analysis of this grouping issue confirmed that, when one of the fourteen hepatic malignancy ICD–10–CM diagnosis codes previously listed is reported as a principal diagnosis with ICD–10–PCS procedure code 04L33DZ, these cases group to MS–DRGs 987, 988, and 989. However, we noted that when one of these fourteen hepatic malignancy ICD–10–CM diagnosis codes is reported as a principal diagnosis with ICD–10–PCS procedure code 04V33DZ, these cases currently group to MS DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). As noted in the previous discussion, whenever there is a surgical procedure reported on the claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in an MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures''.

To understand the resource use for the subset of cases reporting procedure code 04V33DZ with a principal diagnosis of hepatic malignancy that are currently grouping to MS–DRGs 981, 982, and 983, we examined claims data for the average length of stay and average costs for these cases. Our findings are shown in the following table:

MS-DRGs 981 – 983: Cases Reporting Procedure Describing Percutaneous Restriction Of Hepatic Artery With Intraluminal Device with Principal Diagnosis Of Hepatic Malignancy			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
981	17	5.4	$22,447
982	9	6.0	$23,279
983	3	1.3	$10,697

We then examined the claims data to identify cases reporting procedure code 04L33DZ reported with a principal diagnosis of hepatic malignancy that are currently grouping to MS–DRGs 987, 987, and 989. Our findings are shown in the following table:

MS-DRGs 987 – 989: Cases Reporting Procedures Describing Percutaneous Occlusion Of Hepatic Artery With Intraluminal Device with Principal Diagnosis Of Hepatic Malignancy			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
987	107	9.0	$30,179
988	70	4.3	$18,079
989	41	1.7	$10,635

We also examined the data for cases in MS–DRGs 423, 424, and 425, and our findings are shown in the following table:

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
423 – All cases	825	12.2	$29,944
424 – All cases	362	6.8	$16,588
425 – All cases	59	3.5	$11,158

While the average lengths of stay of cases in MS–DRGs 423, 424, and 425 are longer than the average lengths of stay for the subset of cases reporting procedure codes 04V33DZ or 04L33DZ and a principal diagnosis of hepatic malignancy, the average costs of these same cases are generally similar. Our clinical advisors also believe that these procedures are clearly related to the principal diagnoses, as they are an appropriate treatment for a number of hepatobiliary diagnoses, including cancer and it is clinically appropriate for the procedures to group to the same MDC as the principal diagnoses.

Therefore, we are proposing to add ICD–10–PCS procedure codes 04V33DZ and 04L33DZ to MDC 07 in MS–DRGs 423, 424 and 425. Under this proposal, cases reporting procedure codes 04V33DZ or 04L33DZ in conjunction with a principal diagnosis code for a hepatic malignancy from MDC 07 would group to MS–DRGs 423, 424 and 425.

d. Hemoptysis With Percutaneous Artery Embolization

We received a request to reassign cases for hemoptysis when reported with a procedure describing percutaneous embolization of an upper artery with an intraluminal device from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 04. Hemoptysis is the expectoration of blood from some part of the respiratory tract. ICD–10–CM diagnosis code R04.2 (Hemoptysis) is used to report this condition and is currently assigned to MDC 04 (Diseases and Disorders of the Respiratory System). ICD–10–PCS procedure code 03LY3DZ (Occlusion of upper artery with intraluminal device, percutaneous approach) may be reported to describe percutaneous embolization of an upper artery with an intraluminal device and is currently assigned to MDC 05 (Diseases and Disorders of the Circulatory System), MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs) and MDC 24 (Multiple Significant Trauma).

Our analysis of this grouping issue confirmed that when a procedure describing percutaneous embolization of an upper artery with an intraluminal device (such as ICD–10–PCS procedure code 03LY3DZ) is reported with a principal diagnosis from MDC 04, such as R04.2, these cases group to MS–DRGs 981, 982, and 983. During our review of this issue, we also examined claims data for similar procedures 03LY0DZ (Occlusion of upper artery with intraluminal device, open approach) and 03LY4DZ (Occlusion of upper artery with intraluminal device, percutaneous endoscopic approach) and noted the same pattern. As noted in the previous discussion, whenever there is a surgical procedure reported on the claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in an MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures''.

We examined the claims data to identify cases reporting procedure codes 03LY0DZ, 03LY3DZ or 03LY4DZ with a principal diagnosis from MDC 04 that are currently grouping to MS–DRGs 981, 982, and 983. Our findings are shown in this table:

MS-DRGs 981 – 983: Cases Reporting Procedures Describing Percutaneous Embolization Of An Upper Artery with an Intraluminal Device with a Principal Diagnosis in MDC 04			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
981	135	9.3	$32,912
982	69	5.3	$21,235
983	4	2.5	$30,010

As indicated earlier, the requestor suggested that we move ICD–10–PCS procedure code 03LY3DZ to MS–DRGs 163, 164, and 165. However, our clinical advisors believe that, within MDC 04, procedure codes describing percutaneous embolization of an upper artery with an intraluminal device are more clinically aligned with the procedure codes assigned to MS–DRGs 166, 167, and 168 (Other Respiratory System O.R. Procedures with MCC, with CC and without CC/MCC, respectively), as these procedures would not be considered major chest procedures. Therefore, we examined claims data to identify the average length of stay and average costs for cases assigned to MS–DRGs 166, 167 and 168. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
166	11,380	10.3	$26,702
167	6,575	4.9	$13,556
168	2,189	2.6	$10,149

While our clinical advisors noted that the average costs of cases in MS–DRGs 166, 167, and 168 are lower than the average costs for the subset of cases reporting procedure codes 03LY0DZ, 03LY3DZ or 03LY4DZ and a principal diagnosis code from MDC 04, they believe that these procedures are clearly related to the principal diagnoses as these procedures are appropriate for certain respiratory tract diagnoses. Therefore, it is clinically appropriate for the procedures to group to the same MDC as the principal diagnoses.

Therefore, we are proposing to add ICD–10–PCS procedure codes 03LY0DZ, 03LY3DZ and 03LY4DZ to MDC 04 in MS–DRGs 166, 167, and 168. Under this proposal, cases reporting procedure codes 03LY0DZ, 03LY3DZ or 03LY4DZ in conjunction with a principal diagnosis code from MDC 04 such as hemoptysis (R04.2) would group to MS–DRGs 166, 167, and 168.

e. Acquired Coagulation Factor Deficiency With Percutaneous Artery Embolization

We received a request to reassign cases for acquired coagulation factor deficiency when reported with a procedure describing the complete occlusion of an artery with an intraluminal device from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 252, 253 and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively) or 270, 271, and 272 (Other Major Cardiovascular Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 05 (Diseases and Disorders of the Circulatory System). The requestor asked that we reassign ICD–10–CM diagnosis code D68.4 (Acquired coagulation factor deficiency) from MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs, Immunologic Disorders) in MS–DRG 813 (Coagulation Disorders), to MDC 05. The requestor provided the following list of 59 ICD–10–PCS procedure codes describing the complete occlusion of an artery with an intraluminal device in its request for consideration to reassign the ICD–10–CM diagnosis code for acquired coagulation factor deficiency to MDC 05. The requester noted that the diagnosis of Hemorrhage, not elsewhere classified (ICD–10–CM diagnosis code R58) groups to MS–DRGs 252, 253 and 254 or 270, 271, and 272 in MDC 05 when reported with one of the 59 ICD–10–PCS procedure codes listed and requested that cases reporting a diagnosis describing acquired coagulation factor deficiency also group to those MS–DRGs when reported with one of the 59 ICD–10–PCS procedure codes listed.

BILLING CODE 4120–01–P

ICD-10-PCS Code	Code Description
02LQ3DZ	Occlusion right pulmonary artery with intraluminal device, percutaneous approach
02LR3DZ	Occlusion left pulmonary artery with intraluminal device, percutaneous approach
03L53DZ	Occlusion right axillary artery with intraluminal device, percutaneous approach
03L63DZ	Occlusion left axillary artery with intraluminal device, percutaneous approach
03L73DZ	Occlusion right brachial artery with intraluminal device, percutaneous approach
03L83DZ	Occlusion left brachial artery with intraluminal device, percutaneous approach
03L93DZ	Occlusion right ulnar artery with intraluminal device, percutaneous approach
03LB3DZ	Occlusion right radial artery with intraluminal device, percutaneous approach
03LC3DZ	Occlusion left radial artery with intraluminal device, percutaneous approach
03LD3DZ	Occlusion right hand artery with intraluminal device, percutaneous approach
03LF3DZ	Occlusion left hand artery with intraluminal device, percutaneous approach
03LY3DZ	Occlusion upper artery with intraluminal device, percutaneous approach
04LK3DZ	Occlusion right femoral artery with intraluminal device, percutaneous approach
04LL3DZ	Occlusion left femoral artery with intraluminal device, percutaneous approach
04LM3DZ	Occlusion right popliteal artery with intraluminal device, percutaneous approach
04LN3DZ	Occlusion left popliteal artery with intraluminal device, percutaneous approach
04LP3DZ	Occlusion right anterior tibial artery with intraluminal device, percutaneous approach
04LQ3DZ	Occlusion left anterior tibial artery with intraluminal device, percutaneous approach
04LR3DZ	Occlusion right posterior tibial artery with intraluminal device, percutaneous approach
04LS3DZ	Occlusion left posterior tibial artery with intraluminal device, percutaneous approach
04LT3DZ	Occlusion right peroneal artery with intraluminal device, percutaneous approach
04LU3DZ	Occlusion left peroneal artery with intraluminal device, percutaneous approach
04LV3DZ	Occlusion right foot artery with intraluminal device, percutaneous approach
04LW3DZ	Occlusion left foot artery with intraluminal device, percutaneous approach
03L03DZ	Occlusion right internal mammary artery with intraluminal device, percutaneous approach
03L13DZ	Occlusion left internal mammary artery with intraluminal device, percutaneous approach
03L23DZ	Occlusion innominate artery with intraluminal device, percutaneous approach
03L33DZ	Occlusion right subclavian artery with intraluminal device, percutaneous approach
03L43DZ	Occlusion left subclavian artery with intraluminal device, percutaneous approach
03LG3DZ	Occlusion intracranial artery with intraluminal device, percutaneous approach
03LH3DZ	Occlusion right common carotid artery with intraluminal device, percutaneous approach
03LJ3DZ	Occlusion left common carotid artery with intraluminal device, percutaneous approach
03LK3DZ	Occlusion right internal carotid artery with intraluminal device, percutaneous approach
03LL3DZ	Occlusion left internal carotid artery with intraluminal device, percutaneous approach
03LM3DZ	Occlusion right external carotid artery with intraluminal device, percutaneous approach
03LN3DZ	Occlusion left external carotid artery with intraluminal device, percutaneous approach
03LP3DZ	Occlusion right vertebral artery with intraluminal device, percutaneous approach
03LQ3DZ	Occlusion left vertebral artery with intraluminal device, percutaneous approach
03LS3DZ	Occlusion right temporal artery with intraluminal device, percutaneous approach
03LT3DZ	Occlusion left temporal artery with intraluminal device, percutaneous approach
04L13DZ	Occlusion celiac artery with intraluminal device, percutaneous approach
04L23DZ	Occlusion gastric artery with intraluminal device, percutaneous approach
04L33DZ	Occlusion hepatic artery with intraluminal device, percutaneous approach
04L43DZ	Occlusion splenic artery with intraluminal device, percutaneous approach
04L53DZ	Occlusion superior mesenteric artery with intraluminal device, percutaneous approach

ICD-10-PCS Code	Code Description
04L63DZ	Occlusion right colic artery with intraluminal device, percutaneous approach
04L73DZ	Occlusion left colic artery with intraluminal device, percutaneous approach
04L83DZ	Occlusion middle colic artery with intraluminal device, percutaneous approach
04L93DZ	Occlusion right renal artery with intraluminal device, percutaneous approach
04LA3DZ	Occlusion left renal artery with intraluminal device, percutaneous approach
04LB3DZ	Occlusion inferior mesenteric artery with intraluminal device, percutaneous approach
04LC3DZ	Occlusion right common iliac artery with intraluminal device, percutaneous approach
04LD3DZ	Occlusion left common iliac artery with intraluminal device, percutaneous approach
04LE3DZ	Occlusion right internal iliac artery with intraluminal device, percutaneous approach
04LF3DZ	Occlusion left internal iliac artery with intraluminal device, percutaneous approach
04LH3DZ	Occlusion right external iliac artery with intraluminal device, percutaneous approach
04LJ3DZ	Occlusion left external iliac artery with intraluminal device, percutaneous approach
04LY3DZ	Occlusion lower artery with intraluminal device, percutaneous approach

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Our analysis of this grouping issue confirmed that, when diagnosis code D68.4 is reported as a principal diagnosis with one of the 59 ICD–10–PCS procedure codes provided by the requestor, these cases group to MS–DRGs 981, 982, and 983. As noted in the previous discussion, whenever there is a surgical procedure reported on the claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in an MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures''.

We examined the claims data to identify cases involving the 59 procedure codes in MDC 05 reported with a principal diagnosis of code D68.4 that are currently grouping to MS–DRGs 981, 982, and 983. Our analysis showed one case reported a principal diagnosis of D68.4 with a procedure code in MDC 05, with a length of stay of 2.0 days and costs of $21,890 in MS–DRG 981. We found zero cases in MS–DRGs 982 and 983 reporting a procedure code from MDC 05 and a principal diagnosis of code M95.4.

Overall, for MS–DRGs 981, 982, and 983, there was a total of one case reporting a principal diagnosis of acquired coagulation factor deficiency with any of the procedures from MDC 05 provided by the requestor, demonstrating that acquired coagulation factor deficiency is not typically corrected surgically by occlusion of an artery with an intraluminal device.

We also examined the data for cases in MS–DRG 813, and our findings are shown in this table:

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
813	All cases	16,680	4.7	$11,286
	Cases with principal diagnosis D68.4	142	6.4	$17,822

As shown in this table, there were a total of 16,680 cases in MS–DRG 813, with an average length of stay of 4.7 days and average costs of $11,286. In MS–DRG 813, we found 142 cases reporting a principal diagnosis of an acquired coagulation factor deficiency with an average length of stay of 6.41 days and average costs of $17,822. We note that the average costs for the subset of cases in MS–DRG 813 reporting a principal diagnosis of an acquired coagulation factor deficiency are higher than the average costs of all cases that currently group to MS–DRG 813. However, our clinical advisors believe that diagnosis code D68.4 describes acquired bleeding disorders in which the affected person lacks the necessary coagulation factors for proper clot formation and wound healing, and therefore, is most clinically aligned with the diagnosis codes assigned to MDC 16 (where it is currently assigned). Our clinical advisors further note that a diagnosis of an acquired bleeding disorder is not comparable to conditions described by the ICD–10–CM code R58 (Hemorrhage, not elsewhere classified) as suggested by the requestor. Diagnoses described by codes from Chapter 18 (Symptoms, Signs and Abnormal Clinical and Laboratory Findings) of ICD–10–CM, such as R58, can be the result of a variety of underlying conditions, or describe conditions of an unexplained etiology. As an ill-defined condition, our clinical advisors do not believe it is appropriate to equate this diagnosis code with a bleeding disorder. Therefore, we are not proposing to reassign ICD–10–CM diagnosis code D68.4 from MDC 16 to MDC 05.

f. Epistaxis With Percutaneous Artery Embolization

We received a request to consider adding cases for a hemorrhage of the nose when reported with a procedure describing percutaneous arterial embolization to MDC 03 (Disease and Disorders of the Ear, Nose, Mouth and Throat) in MS–DRGs 133 and 134 (Other Ear, Nose, Mouth and Throat O.R. Procedures with CC/MCC and without CC/MCC, respectively). ICD–10–CM diagnosis code R04.0 (Epistaxis) is used to describe a hemorrhage of the nose or ''nosebleed'' and is currently assigned to MDC 03. ICD–10–PCS procedure codes

describing percutaneous arterial embolization may be reported with procedure codes 03LM3DZ (Occlusion of right external carotid artery with intraluminal device, percutaneous approach), 03LN3DZ (Occlusion of left external carotid artery with intraluminal device, percutaneous approach), or 03LR3DZ (Occlusion of face artery with intraluminal device, percutaneous approach) and are currently assigned to several MS–DRGs in five MDCs as illustrated in the table.

MDC	MS-DRG	MS-DRG Description
01	020-022	Intracranial Vascular Procedures with PDX Hemorrhage
01	023-027	Craniotomy
05	270-272	Other Major Cardiovascular Procedures
11	673-675	Other Kidney and Urinary Tract Procedures
21	907-909	Other O.R. Procedures for Injuries
24	957-959	Other Procedures for Multiple Significant Trauma

According to the requestor, when diagnosis code R04.0 is reported as a principal diagnosis with any one of the procedure codes describing a percutaneous arterial embolization (03LM3DZ, 03LN3DZ, or 03LR3DZ), these cases are grouping to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

Our analysis of this grouping issue confirmed that, when epistaxis (ICD–10–CM diagnosis code R04.0) is reported as a principal diagnosis with ICD–10–PCS procedure codes 03LM3DZ, 03LN3DZ, or 03LR3DZ, these cases group to MS–DRGs 981, 982, and 983. The reason for this grouping is because whenever there is a surgical procedure reported on a claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in an MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures.''

For our review of this grouping issue and the request to have cases reporting procedure codes 03LM3DZ, 03LN3DZ, or 03LR3DZ added to MDC 03 in MS–DRGs 133 through 134, we examined claims data from September 2019 update of the FY 2019 MedPAR file for cases reporting ICD–10–PCS procedure codes 03LM3DZ, 03LN3DZ, or 03LR3DZ with a principal diagnosis of R0.40 from MDC 03 that currently group to MS–DRGs 981 through 983. Our findings are shown in the following table.

MS-DRG	ICD-10-PCS code with PDX R04.0	Number of Cases	Average Length of Stay	Average Costs
981	03LM3DZ	19	7.32	$27,984
	03LN3DZ	28	9.36	$36,283
	03LR3DZ	3	4.67	$21,717
982	03LM3DZ	19	4.47	$24,195
	03LN3DZ	43	4.16	$18,698
	03LR3DZ	18	4.06	$17,665
983	03LM3DZ	9	3.44	$16,273
	03LN3DZ	6	1.50	$14,244
	03LR3DZ	1	3.00	$24,270

We then examined the claims data to identify the average length of stay and average costs for all cases in MS–DRGs 133 and 134. Our findings are shown in the table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
133	1,757	5.6	$15,337
134	849	2.5	$9,512

As shown in the table, for MS–DRG 133, there were a total of 1,757 cases with an average length of stay of 5.6 days and average costs of $15,337. For MS–DRG 134, there were a total of 849 cases with an average length of stay of 2.5 days and average costs of $9,512. Our clinical advisors believe that procedure codes 03LM3DZ, 03LN3DZ,

and 03LR3DZ are appropriate procedures to treat commonly occurring ear, nose, and throat bleeding diagnoses and expressed support for these procedure codes to group to MDC 03.

We note that, as discussed in section II.D.4 of the preamble of this proposed rule, we are proposing to delete MS–DRGs 133 and 134 and create proposed new MS–DRGs 143, 144, and 145 (Other Ear, Nose, Mouth and Throat O.R. Procedures with MCC, with CC, and without CC/MCC, respectively). Therefore, we are proposing to add ICD–10–PCS procedure codes 03LM3DZ, 03LN3DZ, and 03LR3DZ to MDC 03 in proposed new MS–DRGs 143, 144, and 145, if finalized. Under this proposal, cases reporting ICD–10–PCS procedure codes 03LM3DZ, 03LN3DZ, or 03LR3DZ with a principal diagnosis from MDC 03 would group to proposed new MS–DRGs 143, 144, and 145.

The following table reflects our simulation for ICD–10–PCS procedure codes 03LM3DZ, 03LN3DZ, and 03LR3DZ in proposed new MS–DRGs 143, 144, and 145.

MS-DRG	ICD-10-PCS code	Number of Cases	Average Length of Stay	Average Costs
143	All cases	709	8.06	$21,408
	03LM3DZ	31	10.60	$29,585
	03LN3DZ	37	8.70	$34,252
	03LR3DZ	10	6.40	$29,418
144	All cases	1,499	4.26	$12,931
	03LM3DZ	19	4.47	$24,195
	03LN3DZ	48	4.30	$18,719
	03LR3DZ	18	4.06	$17,665
145	All cases	1,004	2.42	$9,153
	03LM3DZ	10	3.7	$16,127
	03LN3DZ	7	1.4	$14,925
	03LR3DZ	1	3.00	$24,270

g. Revision or Removal of Synthetic Substitute in Peritoneal Cavity

During the review of the cases that group to MS–DRGs 981 through 983, we noted that when several ICD–10–PCS procedure codes describing revision or removal of synthetic substitute in the peritoneal cavity are reported in conjunction with ICD–10–CM diagnosis codes in MDC 01 (Diseases and Disorders of the Nervous System), such as complications of intracranial shunts, the cases group to MS–DRGs 981 through 983. ICD–10–PCS procedure codes 0WWG0JZ (Revision of synthetic substitute in peritoneal cavity, open approach), 0WWG4JZ (Revision of synthetic substitute in peritoneal cavity, percutaneous endoscopic approach), and 0WPG0JZ (Removal of synthetic substitute from peritoneal cavity, open approach) are currently assigned to MDC 06 (Diseases and Disorders of the Digestive System) in MS–DRGs 356, 357, and 358 (Other Digestive System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively).

We examined cases that reported a principal diagnosis in MDC 01 and procedure code 0WWG0JZ, 0WWG4JZ, or 0WPG0JZ that currently group to MS–DRGs 981 through 983. Our findings are shown in the following table.

MS-DRGs 981 – 983: Cases Reporting Procedures Describing Revision or Removal of Synthetic Substitute in Peritoneal Cavity with a Principal Diagnosis in MDC 01			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
981	77	8.1	$24,463
982	170	4.1	$14,162
983	37	3.6	$11,543

Within MDC 01, our clinical advisors believe that these procedures, which describe revision or removal of synthetic substitute in peritoneal cavity, are most clinically similar to those in MS–DRGs 031, 032, and 033 (Ventricular Shunt Procedures with MCC, with CC, and without CC/MCC, respectively). We therefore examined the data for all cases in MS–DRGS 031, 032, and 033.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
031	844	10.4	$30,275
032	1,898	4.3	$16,257
033	2,604	2.2	$12,601

The average costs for the subset of cases in MS–DRGs 981, 982, and 983 that report procedures describing revision or removal of synthetic substitute in the peritoneal cavity with a principal diagnosis from MDC 01 are lower than the average costs of cases in MS–DRGs 031, 032, and 033 as a whole, and the average length of stay for this subset of cases is also lower in two of the MS–DRGs and higher in one. Our clinical advisors believe the procedure codes describing revision or removal of synthetic substitute in the peritoneal cavity are clearly related to the principal diagnosis codes describing complications of intracranial shunts and, therefore, it is clinically appropriate for the procedures to group to the same MS–DRGs (031, 032, and 033) as the principal diagnoses describing complications of intracranial shunts. We are proposing to add ICD–10–PCS procedure codes 0WWG0JZ, 0WWG4JZ, and 0WPG0JZ to MDC 01 (Diseases and Disorders of the Nervous System) in MS–DRGs 031, 032, and 033.

h. Revision of Totally Implantable Vascular Access Devices

During the review of the cases that group to MS–DRGs 981 through 983, we noted that when procedure codes describing Totally Implantable Vascular Access Devices (TIVADs) are reported with ICD–10–CM diagnosis codes assigned to MDC 04 (Diseases and Disorders of the Respiratory System), MDC 06 (Diseases and Disorders of the Digestive System), MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas), MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue), MDC 13 (Diseases and Disorders of the Female Reproductive System), or MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs, Immunologic Disorders), the cases group to MS–DRGs 981 through 983.

TIVADs are port catheter devices inserted for chemotherapy treatment. The nine ICD–10–PCS procedure codes describing TIVADs are listed in this table.

ICD-10-PCS Code	Code Description
0JH60WZ	Insertion of totally implantable vascular access device into chest subcutaneous tissue and fascia, open approach
0JH80WZ	Insertion of totally implantable vascular access device into abdomen subcutaneous tissue and fascia, open approach
0JHD0WZ	Insertion of totally implantable vascular access device into right upper arm subcutaneous tissue and fascia, open approach
0JHF0WZ	Insertion of totally implantable vascular access device into left upper arm subcutaneous tissue and fascia, open approach
0JHG0WZ	Insertion of totally implantable vascular access device into right lower arm subcutaneous tissue and fascia, open approach
0JHH0WZ	Insertion of totally implantable vascular access device into left lower arm subcutaneous tissue and fascia, open approach
0JHL0WZ	Insertion of totally implantable vascular access device into right upper leg subcutaneous tissue and fascia, open approach
0JHM0WZ	Insertion of totally implantable vascular access device into left upper leg subcutaneous tissue and fascia, open approach
0JHP0WZ	Insertion of totally implantable vascular access device into left lower leg subcutaneous tissue and fascia, open approach

We examined claims data to identify the average length of stay and average costs for cases in MS–DRGs 981 through 983 reporting ICD–10–PCS procedure codes describing TIVADs in conjunction with a principal diagnosis from MDCs 04, 06, 07, 08, 13, or 16. Our findings are shown in the following table.

MS-DRGs 981 – 983: Cases Reporting Procedures Describing Insertion of Totally Implantable Vascular Access Devices				
MDC	MS-DRG	Number of Cases	Average Length of Stay	Average Costs
04	981	427	10.3	$22,526
	982	244	6.5	$13,661
	983	11	3.4	$8,761
06	981	259	10.3	$24,003
	982	281	6.9	$13,712
	983	15	3.1	$9,688
07	981	172	10.3	$22,176
	982	113	6.3	$13,227
	983	2	3.5	$7,471
08	981	32	12.2	$24,424
	982	38	7.8	$16,531
	983	2	7.5	$16,693
13	981	38	11.3	$22,095
	982	43	7.5	$14,858
	983	0	-	$ -
16	981	30	10.1	$23,765
	982	64	6.4	$16,726
	983	15	5.2	$26,932

Our clinical advisors believe that cases reporting TIVADs with a principal diagnosis in MDCs 04, 06, 07, 08, 13, or 16 would most suitably group to the MS–DRGs describing ''Other'' procedures for each of these MDCs. These TIVAD procedures cannot be assigned to the specific surgical MS–DRGs within these MDCs since they are not performed on the particular anatomical areas described by each of the specific surgical MS–DRGs. For example, in MDC 04, TIVADs could not be assigned to MS–DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC, and without CC/MCC, respectively) because they are not major chest procedures.

We therefore examined the claims data for each of these MS–DRGs. Our findings are shown in the following table.

MDC	MS-DRG	MS-DRG Description	Number of Cases	Average Length of Stay	Average Costs
04	166	Other Respiratory System O.R. Procedures with MCC, with CC, without CC/MCC respectively	11,380	10.3	$26,702
	167		6,575	4.9	$13,556
	168		2,189	2.6	$10,149
06	356	Other Digestive System O.R. Procedures with MCC, with CC, without CC/MCC respectively	7,525	10.4	$30,071
	357		5,759	5.8	$16,452
	358		1,191	3.4	$10,031
07	423	Other Hepatobiliary or Pancreas O.R. Procedures with MCC, with CC, without CC/MCC respectively	825	12.2	$29,944
	424		362	6.8	$16,588
	425		59	3.5	$11,158
08	515	Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC, without CC/MCC respectively	4,655	8.2	$22,176
	516		13,308	4.6	$14,225
	517		11,992	2.6	$10,318
13	749	Other Female Reproductive System O.R. Procedures with CC/MCC, without CC/MCC respectively	695	8	$21,582
	750		99	2.9	$10,907
16	802	Other O.R. Procedures of the Blood and Blood Forming Organs with MCC, with CC, without CC/MCC respectively	849	10.1	$25,238
	803		894	5.2	$13,689
	804		414	2.5	$9,503

We note that while the average costs and length of stay are similar in some cases and in some cases vary between the subset of cases currently grouping to MS–DRGs 981 through 983 and the cases currently grouping to the MS–DRGs describing ''Other'' procedures as set forth in the table, our clinical advisors noted that TIVADs are frequently inserted in order to administer chemotherapy for a variety of malignancies. MDCs 04, 06, 07, 08, 13, or 16 each contain ICD–10–CM diagnosis codes that describe a variety of malignancies. Therefore, our clinical advisors believe that the TIVAD procedures are clearly related to the principal diagnoses within MDCs 04, 06, 07, 08, 13, and 16. For the reasons previously indicated, our clinical advisors believe that cases reporting TIVADs with a principal diagnosis in MDCs 04, 06, 07, 08, 13, or 16 would mostly suitably group to the MS–DRGs describing ''Other'' procedures for each of these MDCs.

Therefore, we are proposing to add the nine ICD–10–PCS procedure codes describing TIVADs as set forth in the table to the MS–DRGs describing ''Other'' procedures within each of MDCs 04, 06, 07, 08, 13, and 16, specifically: MDC 04 in MS–DRGs 166, 167, and 168, MDC 06 in MS–DRGs 356, 357, and 358, MDC 07 in MS–DRGs 423, 424, and 425, MDC 08 in MS–DRGs 515, 516, and 517, MDC 13 in MS–DRGs 749 and 750, and MDC 16 in MS–DRGs 802, 803, and 804. Under this proposal, cases reporting a principal diagnosis in MDCs 04, 06, 07, 08, 13, or 16 with a TIVAD procedure would group to the respective MS–DRGs within the MDC.

i. Multiple Trauma With Internal Fixation of Joints

For FY 2020, we received a request to reassign cases involving diagnoses that identify multiple significant trauma combined with internal fixation of joint procedures from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 957, 958, and 959 (Other O.R. Procedures for Multiple Significant Trauma with MCC, with CC, and without CC/MCC, respectively) in MDC 24 (Multiple Significant Trauma). The requestor provided an example of several ICD–10–CM diagnosis codes that together described multiple significant trauma in conjunction with ICD–10–PCS procedure codes beginning with the prefix ''0RH'' and ''0SH'' that describe internal fixation of upper and lower joints. The requestor provided several suggestions to address this reassignment, including: Adding all ICD–10–PCS procedure codes from MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) with the exception of codes that group to MS–DRG 956 (Limb Reattachment, Hip and Femur Procedures for Multiple Significant Trauma) to MS DRGs 957, 958, and 959; adding codes with the prefix ''0RH'' and ''0SH'' to MDC 24; and adding ICD–10–PCS procedure codes from all MDCs except those that currently group to MS–DRG 955 (Craniotomy for Multiple Significant Trauma) or MS–DRG 956 (Limb Reattachment, Hip and Femur Procedures for Multiple Significant Trauma) to MS–DRGs 957, 958, and 959 in MDC 24. In the FY 2020 IPPS/LTCH PPS proposed rule, we stated that we believe any potential reassignment of these cases requires significant analysis. We therefore did not propose any changes to the cases identified by the requestor.

For FY 2021, as the first step of the comprehensive analysis needed to assess the reassignment of cases involving diagnoses that identify multiple significant trauma combined with internal fixation of joint procedures, our clinical advisors reviewed the list of procedure codes in the ''0RH'' and ''0SH'' code ranges, as

suggested by the requestor. Our clinical advisors identified 161 ICD–10–PCS codes, which are listed in table 6P.1f., that they believe are clinically related to diagnoses assigned to MDC 24. We examined the claims data for cases that would be assigned to MDC 24 based on their diagnoses, but currently group to MS–DRGs 981 through 983 based on the presence of procedure codes in the ''0RH'' and ''0SH'' code ranges. Our findings are shown in this table.

ICD-10-PCS Code	Code Description	Number of Cases	Length of Stay	Cost
0SHB04Z	Insertion of internal fixation device into left hip joint, open approach	1	4	$54,446
0SH834Z	Insertion of internal fixation device into left sacroiliac joint, percutaneous approach	1	14	$30,992
0SH334Z	Insertion of internal fixation device into lumbosacral joint, percutaneous approach	1	6	$22,118
0RH634Z	Insertion of internal fixation device into thoracic vertebral joint, percutaneous approach	1	11	$56,631
0RH634Z	Insertion of internal fixation device into thoracic vertebral joint, percutaneous approach	1	10	$72,331
0RH604Z	Insertion of internal fixation device into thoracic vertebral joint, open approach	1	8	$15,857
0SH834Z	Insertion of internal fixation device into left sacroiliac joint, percutaneous approach	1	12	$32,489
0SHB04Z	Insertion of internal fixation device into left hip joint, open approach	1	3	$7,015

We note that we found only 8 claims, with varying lengths of stay and average costs. We also examined the claims data for all cases in MS–DRGs 957, 958, and 959. Our findings are shown in this table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
957	1,966	13.2	$54,771
958	1,605	8.2	$30,701
959	114	5	$20,563

The very small number of claims we identified for cases that would be assigned to MDC 24 based on their diagnoses, but grouped to MS–DRGs 981 through 983 based on the presence of procedure codes in the ''0RH'' and ''0SH'' code ranges, have varying resource use relative to MS–DRGs 957, 958, and 959 as a whole. The average costs of the cases found in MS–DRGs 981–983 range from $7,015 to $72,331 with average lengths of stay ranging from 3 days to 14 days. The average costs of the cases found in MS–DRGs 957–959 range from $20,563 to $54,771 with average lengths of stay ranging from 5 days to 13.2 days. Given the nature of trauma cases, the resource use would be expected to vary based on the nature of the patient's injuries. In addition, as noted, our clinical advisors believe that these procedure codes are clinically related to the diagnoses in MDC 24. Therefore, we are proposing to add the 161 ICD–10–PCS codes shown in Table 6P.1f to MDC 24 in MS–DRGs 957, 958, and 959. Under this proposal, cases that would be assigned to MDC 24 based on their diagnoses, that also report one of the 161 ICD–10–PCS codes included in table 6P.1f, will group to MDC 24 in MS–DRGs 957, 958, and 959, rather than to MS–DRGs 981 through 983.

We note that while we are making this proposal to address the grouping issue for internal fixation of upper and lower joint procedures identified by the requestor, our clinical advisors believe that a more comprehensive analysis is required within MDC 24 to address the differences in severity level of diagnoses as well as the assignment of procedure codes to the MS–DRGs within MDC 24. We plan to continue this comprehensive analysis in future rulemaking.

j. Reassignment of Procedures Among MS–DRGs 981 Through 983 and 987 Through 989

We also review the list of ICD–10–PCS procedures that, when in combination with their principal diagnosis code, result in assignment to MS–DRGs 981 through 983, or 987 through 989, to ascertain whether any of those procedures should be reassigned from one of those two groups of MS–DRGs to the other group of MS–DRGs based on average costs and the length of stay. We look at the data for trends such as shifts in treatment practice or reporting practice that would make the resulting MS–DRG assignment illogical. If we find these shifts, we would propose to move cases to keep the MS–DRGs clinically similar or to provide payment for the cases in a similar manner. Generally, we move only those procedures for which we have an adequate number of discharges to analyze the data.

Based on the results of our review of claims data in the September 2019 update of the FY 2019 MedPAR file, we are proposing to reassign three procedure codes from MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, without CC/MCC, respectively) to MS–DRGs 987, 988, and 989 (Non-Extensive Procedure Unrelated to Principal Diagnosis with MCC, with CC, without CC/MCC, respectively). We are also proposing to reassign three procedure codes from MS–DRGs 987, 988, and 989 (Non-Extensive Procedure Unrelated to Principal Diagnosis with MCC, with CC, without CC/MCC, respectively) to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, without CC/MCC, respectively).

In conducting our review of the request to designate ICD–10–PCS procedure code 0W3G0ZZ (Control bleeding in peritoneal cavity, open approach) as an O.R. procedure (as described in section II.D.11.c.5. of this proposed rule), our clinical advisors noted that ICD–10–PCS codes 0W3G3ZZ (Control bleeding in peritoneal cavity, percutaneous approach) and 0W3G4ZZ (Control bleeding in peritoneal cavity, endoscopic approach) are currently assigned to MS–DRGs 981 through 983 when reported with a principal diagnosis that is not assigned to one of the MDCs to which these procedure codes are assigned. Our clinical advisors believe that these procedures would be more appropriately assigned to MS–DRGs 987 through 989 because they are on average less complex and difficult than the same procedure performed by an open approach, and therefore should be assigned to the ''less extensive'' DRG. Therefore, we are proposing to reassign ICD–10–PCS codes 0W3G3ZZ and 0W3G4ZZ from MS–DRGs 981 through 983 to 987 through 989.

In conducting our review of the request to designate ICD–10–PCS procedure codes 0WBC4ZX (Excision of mediastinum, percutaneous endoscopic

approach, diagnostic) and 0WBC3ZX (Excision of mediastinum, percutaneous approach, diagnostic) as O.R. procedures (as described in section II.D.11.c.1. of this proposed rule), our clinical advisors noted that ICD–10–PCS code 0WBC0ZX (Excision of mediastinum, open approach, diagnostic) is currently assigned to MS–DRGs 981 through 983 when reported with a principal diagnosis that is not assigned to one of the MDCs to which the procedure code is assigned. Our clinical advisors believe that this procedure would be more appropriately assigned to MS–DRGs 987 through 989 because this assignment is consistent with the assignment of other procedures that describe excision of the mediastinum performed by an open, percutaneous, or percutaneous endoscopic approach, and is consistent with the proposal for procedure codes 0WBC4ZX and 0WBC3ZX (with diagnostic qualifier) as discussed in section II.D.11.c.1. of this proposed rule. Therefore, we are proposing to reassign ICD–10–PCS code 0WBC0ZX from MS–DRGs 981 through 983 to 987 through 989.

We received a request to examine cases reporting a procedure describing the open excision of gastrointestinal body parts in the gastrointestinal body system. The requester stated that when procedures describing the open excision of a specific gastrointestinal body part in the gastrointestinal body system are reported with a principal diagnosis such as C49.A3 (Gastrointestinal stromal tumor of small intestine (GIST)), the cases are assigned to MS–DRGs 987, 988, and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). However, when procedures describing the excision of a general gastrointestinal body part in the gastrointestinal body system are reported with the same principal diagnosis of GIST, the cases are assigned to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). The requestor stated that procedures describing a specific body part value should be assigned to the same MS–DRG as procedures describing a general body part value.

The requestor provided four ICD–10–PCS procedure codes in its request. These four ICD–10–PCS procedure codes, as well as their MDC assignments, are listed in the table:

ICD-10-PCS Code	Code Description	MDC
0DB90ZZ	Excision of duodenum, open approach	06,07,17
0DBA0ZZ	Excision of jejunum, open approach	06
0DBB0ZZ	Excision of ileum, open approach	06
0DB80ZZ	Excision of small intestine, open approach	05,06,10,17,21,24

We note that in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42120 through 42122), we finalized our proposal to move seven ICD–10–CM diagnosis codes describing gastrointestinal stromal tumors (GIST), including C49.A3, from MDC 08 to MDC 06, under the ICD–10 MS–DRGs Version 37, effective October 1, 2019. As a result, cases reporting a principal diagnosis of GIST and a procedure code that is assigned to MDC 06 (such as ICD–10–PCS codes 0DBA0ZZ, 0DBB0ZZ, 0DB80ZZ, and 0DB90ZZ) now group to MS–DRGs in MDC 06.

Our analysis of this grouping issue found that these four ICD–10–PCS codes describing related procedures have dissimilar designations that determine whether and in what way the presence of the procedure impacts the MS–DRG assignment. ICD–10–PCS code 0DB80ZZ is classified as an extensive O.R. procedure and ICD–10–PCS codes 0DB90ZZ, 0DBA0ZZ, and 0DBB0ZZ are classified as non-extensive O.R. procedures. As a result, whenever ICD–10–PCS code 0DB80ZZ is reported with a principal diagnosis that is assigned to a different MDC than the procedure code, the case would be assigned to MS–DRGs 981 through 983. When ICD–10–PCS codes 0DB90ZZ, 0DBA0ZZ, or 0DBB0ZZ are reported with a principal diagnosis that is assigned to a different MDC than the procedure code, the case would be assigned to MS–DRGs 987 through 989.

We examined the claims data to identify cases reporting procedure code 0DB80ZZ that are currently grouping to MS–DRGs 981, 982 and 983. Our findings are shown in this table:

MS-DRGs 981 – 983: Cases Reporting Procedures Describing Excision of Small Intestine, Open Approach				
MS-DRG	**ICD-10-PCS codes**	**Number of Cases**	**Average Length of Stay**	**Average Costs**
981	All cases	25,914	11.4	$31,281
	0DB80ZZ	66	15.8	$42,198
982	All cases	13,990	6.2	$17,714
	0DB80ZZ	21	8.9	$16,995
983	All cases	2,572	3	$12,194
	0DB80ZZ	4	3	$10,619

We also examined the claims data to identify cases reporting procedure codes 0DB90ZZ, 0DBA0ZZ, and 0DBB0ZZ that are currently grouping to MS–DRGs 987, 988 and 989. Our findings are shown in this table:

MS-DRGs 987 – 989: Cases Reporting Procedures Describing Excision of Duodenum, Jejunum, or Ileum, Open Approach				
MS-DRG	**ICD-10-PCS codes**	**Number of Cases**	**Average Length of Stay**	**Average Costs**
987	All cases	8,266	10.3	$23,442
	0DB90ZZ	2	25	$78,148
	0DBA0ZZ	5	8.2	$39,885
	0DBB0ZZ	30	17.5	$36,683
988	All cases	7,566	5.7	$12,426
	0DB90ZZ	1	6	$5,438
	0DBA0ZZ	3	7.7	$14,713
	0DBB0ZZ	41	10.9	$22,876
989	All cases	1,140	3	$8,095
	0DB90ZZ	0	0	$0
	0DBA0ZZ	2	2	$5,087
	0DBB0ZZ	27	6.8	$10,775

The results of our data analysis indicate that cases reporting procedure codes 0DB90ZZ, 0DBA0ZZ, and 0DBB0ZZ describing the open excision of a specific gastrointestinal body part in MS–DRGs 987, 988, and 989 generally have a longer length of stay and higher average costs when compared to all the cases in their assigned MS–DRG. The subset of cases reporting 0DB90ZZ, 0DBA0ZZ, and 0DBB0ZZ and the subset of cases in MS–DRGs 981, 982 and 983 reporting 0DB80ZZ are more closely aligned in terms of the lengths of stay and average costs. Our clinical advisors believe that, given the similarity in resource use required for procedures describing an open excision of a gastrointestinal body part in terms of the use of an operating room, anesthesia and skills required, for clinical coherence and consistency in assignment with ICD–10–PCS code 0DB80ZZ, it would be appropriate to also designate ICD–10–PCS codes 0DB90ZZ, 0DBA0ZZ, and 0DBB0ZZ as extensive O.R. procedures.

Therefore, we are proposing to change the designation of ICD–10–PCS codes 0DB90ZZ, 0DBA0ZZ and 0DBB0ZZ from non-extensive O.R. procedures to extensive O.R. procedures for FY 2021. Under this proposal, cases reporting procedure codes 0DB90ZZ, 0DBA0ZZ and 0DBB0ZZ, which are unrelated to the MDC to which the case would otherwise be assigned based on the principal diagnosis, will group to MS–DRGs 981, 982 and 983.

11. Operating Room (O.R.) and Non-O.R. Issues

a. Background

Under the IPPS MS–DRGs (and former CMS MS–DRGs), we have a list of procedure codes that are considered operating room (O.R.) procedures. Historically, we developed this list using physician panels that classified each procedure code based on the procedure and its effect on consumption

of hospital resources. For example, generally the presence of a surgical procedure which required the use of the operating room would be expected to have a significant effect on the type of hospital resources (for example, operating room, recovery room, and anesthesia) used by a patient, and therefore, these patients were considered surgical. Because the claims data generally available do not precisely indicate whether a patient was taken to the operating room, surgical patients were identified based on the procedures that were performed. Generally, if the procedure was not expected to require the use of the operating room, the patient would be considered medical (non-O.R.).

Currently, each ICD–10–PCS procedure code has designations that determine whether and in what way the presence of that procedure on a claim impacts the MS–DRG assignment. First, each ICD–10–PCS procedure code is either designated as an O.R. procedure for purposes of MS–DRG assignment (''O.R. procedures'') or is not designated as an O.R. procedure for purposes of MS–DRG assignment (''non-O.R. procedures''). Second, for each procedure that is designated as an O.R. procedure, that O.R. procedure is further classified as either extensive or non-extensive. Third, for each procedure that is designated as a non-O.R. procedure, that non-O.R. procedure is further classified as either affecting the MS–DRG assignment or not affecting the MS–DRG assignment. We refer to these designations that do affect MS–DRG assignment as ''non-O.R. affecting the MS–DRG.'' For new procedure codes that have been finalized through the ICD–10 Coordination and Maintenance Committee meeting process and are proposed to be classified as O.R. procedures or non-O.R. procedures affecting the MS–DRG, our clinical advisors recommend the MS–DRG assignment which is then made available in association with the proposed rule (Table 6B.—New Procedure Codes) and subject to public comment. These proposed assignments are generally based on the assignment of predecessor codes or the assignment of similar codes. For example, we generally examine the MS–DRG assignment for similar procedures, such as the other approaches for that procedure, to determine the most appropriate MS–DRG assignment for procedures proposed to be newly designated as O.R. procedures. As discussed in section II.D.13 of the preamble of this proposed rule, we are making Table 6B.—New Procedure Codes—FY 2021 available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. We also refer readers to the ICD–10 MS–DRG Version 37 Definitions Manual at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS–DRG-Classifications-and-Software.html* for detailed information regarding the designation of procedures as O.R. or non-O.R. (affecting the MS–DRG) in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index.

In the FY 2020 IPPS/LTCH PPS proposed rule, we stated that, given the long period of time that has elapsed since the original O.R. (extensive and non-extensive) and non-O.R. designations were established, the incremental changes that have occurred to these O.R. and non-O.R. procedure code lists, and changes in the way inpatient care is delivered, we plan to conduct a comprehensive, systematic review of the ICD–10–PCS procedure codes. This will be a multi-year project during which we will also review the process for determining when a procedure is considered an operating room procedure. For example, we may restructure the current O.R. and non-O.R. designations for procedures by leveraging the detail that is now available in the ICD–10 claims data. We refer readers to the discussion regarding the designation of procedure codes in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38066) where we stated that the determination of when a procedure code should be designated as an O.R. procedure has become a much more complex task. This is, in part, due to the number of various approaches available in the ICD–10–PCS classification, as well as changes in medical practice. While we have typically evaluated procedures on the basis of whether or not they would be performed in an operating room, we believe that there may be other factors to consider with regard to resource utilization, particularly with the implementation of ICD–10. Therefore, we are again soliciting feedback on what factors or criteria to consider in determining whether a procedure is designated as an O.R. procedure in the ICD–10–PCS classification system for future consideration. Commenters should submit their recommendations to the following email address: *MSDRGClassificationChange@cms.hhs.gov* by October 20, 2020.

We discussed in the FY 2020 IPPS/LTCH PPS proposed rule that as a result of this planned review and potential restructuring, procedures that are currently designated as O.R. procedures may no longer warrant that designation, and conversely, procedures that are currently designated as non-O.R. procedures may warrant an O.R. type of designation. We intend to consider the resources used and how a procedure should affect the MS–DRG assignment. We may also consider the effect of specific surgical approaches to evaluate whether to subdivide specific MS–DRGs based on a specific surgical approach. We plan to utilize our available MedPAR claims data as a basis for this review and the input of our clinical advisors. As part of this comprehensive review of the procedure codes, we also intend to evaluate the MS–DRG assignment of the procedures and the current surgical hierarchy because both of these factor into the process of refining the ICD–10 MS–DRGs to better recognize complexity of service and resource utilization.

We will provide more detail on this analysis and the methodology for conducting this review in future rulemaking. As we noted in the FY 2020 IPPS/LTCH PPS rulemaking, as we continue to develop our process and methodology, as previously noted, we are soliciting recommendations on other factors to consider in our refinement efforts to recognize and differentiate consumption of resources for the ICD–10 MS–DRGs.

In this proposed rule, we are addressing requests that we received regarding changing the designation of specific ICD–10–PCS procedure codes from non-O.R. to O.R. procedures, or changing the designation from O.R. procedure to non-O.R. procedure. In this section of the rule we discuss the process that was utilized for evaluating the requests that were received for FY 2021 consideration. For each procedure, our clinical advisors considered—

- Whether the procedure would typically require the resources of an operating room;
- Whether it is an extensive or a nonextensive procedure; and
- To which MS–DRGs the procedure should be assigned.

We note that many MS–DRGs require the presence of any O.R. procedure. As a result, cases with a principal diagnosis associated with a particular MS–DRG would, by default, be grouped to that MS–DRG. Therefore, we do not list these MS–DRGs in our discussion in this section of this rule. Instead, we only discuss MS–DRGs that require explicitly adding the relevant procedure codes to the GROUPER logic in order for those procedure codes to affect the MS–DRG assignment as intended. In cases where

we are proposing to change the designation of procedure codes from non-O.R. procedures to O.R. procedures, we also are proposing one or more MS–DRGs with which these procedures are clinically aligned and to which the procedure code would be assigned.

In addition, cases that contain O.R. procedures will map to MS–DRG 981, 982, or 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRG 987, 988, or 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) when they do not contain a principal diagnosis that corresponds to one of the MDCs to which that procedure is assigned. These procedures need not be assigned to MS–DRGs 981 through 989 in order for this to occur. Therefore, if requestors included some or all of MS–DRGs 981 through 989 in their request or included MS–DRGs that require the presence of any O.R. procedure, we did not specifically address that aspect in summarizing their request or our response to the request in this section of this rule.

For procedures that would not typically require the resources of an operating room, our clinical advisors determined if the procedure should affect the MS–DRG assignment.

We received several requests to change the designation of specific ICD–10–PCS procedure codes from non-O.R. procedures to O.R. procedures, or to change the designation from O.R. procedures to non-O.R. procedures. In this section of this rule, we detail and respond to some of those requests. With regard to the remaining requests, our clinical advisors believe it is appropriate to consider these requests as part of our comprehensive review of the procedure codes as previously discussed.

b. O.R. Procedures to Non-O.R. Procedures

(1) Endoscopic Revision of Feeding Devices

One requestor identified three ICD–10–PCS procedure codes that describe endoscopic revision of feeding devices, shown in the following table.

ICD-10-PCS Code	Code Description
0DW08UZ	Revision of feeding device in upper intestinal tract, via natural or artificial opening endoscopic
0DW68UZ	Revision of feeding device in stomach, via natural or artificial opening endoscopic
0DWD8UZ	Revision of feeding device in lower intestinal tract, via natural or artificial opening endoscopic

In the ICD–10 MS–DRG Version 37 Definitions Manual, these three ICD–10–PCS procedure codes are currently recognized as O.R. procedures for purposes of MS–DRG assignment. The requestor noted that these procedures would not require the resources of an operating room and that they consume resources comparable to related ICD–10–PCS procedure codes describing the endoscopic insertion of feeding tubes that currently are designated as Non-O.R. procedures.

We agree with the requestors that these procedures do not typically require the resources of an operating room, and are not surgical in nature. Therefore, we are proposing to remove 0DW08UZ, 0DW68UZ, 0DWD8UZ from the FY 2021 ICD–10 MS–DRGs Version 38 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures. Under this proposal, these procedures would no longer impact MS–DRG assignment.

c. Non-O.R. Procedures to O.R. Procedures

(1) Percutaneous/Endoscopic Biopsy of Mediastinum

One requestor identified ICD–10–PCS procedure code 0WBC4ZX (Excision of mediastinum, percutaneous endoscopic approach, diagnostic) that describes a percutaneous endoscopic biopsy of the mediastinum that the requestor stated is performed in the operating room under general anesthesia, requires an incision through the chest wall, insertion of a mediastinoscope in the space between the lungs and involves removal of a tissue sample. The requestor recommended that all procedures performed within the mediastinum by an open or percutaneous endoscopic approach, regardless of whether it is a diagnostic or therapeutic procedure, should be designated as O.R. procedures because the procedures require great skill and pose risks to patients due to the structures contained within the mediastinum. The requestor noted that the mediastinum contains loose connective tissue, the heart and great vessels, esophagus, trachea, nerves, and lymph nodes. The requestor further noted that redesignating these procedures from non-O.R. to O.R. would provide compensation for operating room resources and general anesthesia.

We note that under the ICD–10–PCS procedure classification, biopsy procedures are identified by the 7th digit qualifier value ''diagnostic'' in the code description. In response to the requestor's suggestion that all procedures performed within the mediastinum by an open or percutaneous endoscopic approach, regardless of whether it is a diagnostic or therapeutic procedure should be designated as an O.R. procedure, we examined the following procedure codes:

ICD-10-PCS Code	Description
0WBC0ZX	Excision of mediastinum, open approach, diagnostic
0WBC0ZZ	Excision of mediastinum, open approach
0WBC3ZX	Excision of mediastinum, percutaneous approach, diagnostic
0WBC3ZZ	Excision of mediastinum, percutaneous approach
0WBC4ZX	Excision of mediastinum, percutaneous endoscopic approach, diagnostic
0WBC4ZZ	Excision of mediastinum, percutaneous endoscopic approach

In the ICD–10 MS–DRGs Definitions Manual Version 37, procedure codes 0WBC0ZX, 0WBC0ZZ, 0WBC3ZZ, and 0WBC4ZZ are currently designated as O.R. procedures, however, procedure codes 0WBC3ZX and 0WBC4ZX are not recognized as O.R. procedures for purposes of MS–DRG assignment. We agree with the requestor that procedure code 0WBC4ZX would typically require the resources of an operating room. Our clinical advisors also agree that procedure code 0WBC3ZX would typically require the resources of an operating room. Therefore, we are proposing to add these 2 procedure codes to the FY 2021 ICD–10 MS–DRGs Version 38 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures, assigned to MS–DRGs 166, 167, and 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 04 (Diseases and Disorders of the Respiratory System); MS–DRGs 628, 629, and 630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders); MS–DRGs 820, 821, and 822 (Lymphoma and Leukemia with Major O.R. Procedure with MCC, with CC, and without CC/MCC, respectively) and MS–DRGs 826, 827, and 828 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedure with MCC, with CC, and without CC/MCC, respectively) in MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms); and to MS–DRGs 987, 988, and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without MCC/CC, respectively).

As previously noted, procedure codes 0WBC0ZX, 0WBC0ZZ, 0WBC3ZZ, and 0WBC4ZZ are currently designated as O.R. procedures. As displayed in the FY 2020 ICD–10 MS–DRGs Version 37 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index, these procedure codes are assigned to several MS–DRGs across many MDCs. During our process of reviewing potential MDC and MS–DRG assignments for procedure codes 0WBC3ZX and 0WBC4ZX, our clinical advisors recommended that we reassign procedure codes 0WBC0ZZ, 0WBC3ZZ, and 0WBC4ZZ from their current MS–DRG assignments in MDC 04 (Diseases and Disorders of the Respiratory System). Procedure codes 0WBC0ZZ, 0WBC3ZZ, and 0WBC4ZZ are currently assigned to MS–DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC, and without CC/MCC, respectively) and procedure code 0WBC0ZX is assigned to MS–DRGs 166, 167, and 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively). According to our clinical advisors, procedure codes 0WBC0ZZ, 0WBC3ZZ, and 0WBC4ZZ would be more appropriately and clinically aligned with the same MS–DRG assignment as procedure code 0WBC0ZX, which is also consistent with the assignment for other procedures performed on the mediastinum. Therefore, we are proposing to reassign procedure codes 0WBC0ZZ, 0WBC3ZZ, and 0WBC4ZZ to MS–DRGs 166, 167, and 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively).

(2) Percutaneous Endoscopic Chemical Pleurodesis

One requestor identified ICD–10–PCS procedure code 3E0L4GC (Introduction of other therapeutic substance into pleural cavity, percutaneous endoscopic approach) that the requestor stated is currently not recognized as an O.R. procedure for purposes of MS–DRG assignment. The requestor noted that talc pleurodesis via video-assisted thoracoscopic surgery (VATS), involves placing a thoracoscope through the chest wall for visualization, then placing a port and injecting talc, doxycycline, or other chemical into the pleural cavity under general anesthesia and should therefore be recognized as an O.R. procedure for purposes of MS–DRG assignment.

We agree with the requestor that ICD–10–PCS procedure code 3E0L4GC typically requires the resources of an operating room. We also note that the AHA published Coding Clinic advice in 2015 that instructed to code both ICD–10–PCS procedure codes 0BJQ4ZZ (Inspection of pleura, percutaneous endoscopic approach) and 3E0L3GC (Introduction of other therapeutic substance into pleural cavity, percutaneous approach) for thoracoscopic chemical pleurodesis. In the publication, code 0BJQ4ZZ, recognized as an O.R. procedure for purposes of MS–DRG assignment, was instructed to be reported for the video-assisted thoracoscopic portion of the procedure since the endoscopic component of the procedure could not be captured by the approach values available at the time. In FY 2018, the approach value ''4'' Percutaneous Endoscopic was added to the root operation Introduction table 3E0, to capture percutaneous endoscopic administration of a therapeutic substance, meaning that code 0BJQ4ZZ was no longer needed along with code 3E0L3GC to report thoracoscopic chemical pleurodesis. Only code 3E0L4GC is needed to report all components of the procedure. Designating code 3E0L4GC as an O.R. procedure for purposes of MS–DRG assignment classifies the procedure as intended when two codes were needed to fully code the procedure. Therefore, we are proposing to add procedure code 3E0L4GC to the FY 2021 ICD–10 MS–DRG Version 38 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as an O.R. procedure assigned to MS–DRGs 166, 167, and 168 (Other Respiratory System O.R. procedures with MCC, CC, without CC/MCC, respectively) in MDC 04 (Diseases and Disorders of the Respiratory System); and MS–DRG 264 (Other Circulatory System O.R. Procedures) in MDC 05 (Diseases and Disorders of the Circulatory System).

(3) Percutaneous Endoscopic Excision of Stomach

One requestor identified ICD–10–PCS procedure code 0DB64ZZ (Excision of stomach, percutaneous endoscopic approach) that the requestor stated is currently not recognized as an O.R. procedure for purposes of MS–DRG assignment. The requestor noted that percutaneous endoscopic excisions of gastric lesions and percutaneous endoscopic partial gastrectomies are performed in the operating room under general anesthesia, use comparable resources, and are designated as O.R. procedures. Therefore, the requestor stated that this procedure should also be recognized as O.R. procedure for purposes of MS–DRG assignment.

We agree with the requestor that ICD–10–PCS procedure code 0DB64ZZ typically requires the resources of an operating room. During our review, we also noted that ICD–10–PCS code 0DB64ZX (Excision of stomach, percutaneous endoscopic approach, diagnostic) was not currently recognized as an O.R. procedure. We are proposing to add these codes to the FY 2021 ICD–10 MS–DRG Version 38 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as an O.R. procedure assigned to MS–DRGs 326, 327, and 328 (Stomach, Esophageal and Duodenal Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 06 (Diseases and Disorders of the Digestive System); MS–DRGs 619, 620, and 621 (Procedures for Obesity with MCC, with CC, and without CC/MCC, respectively) in MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders); and MS–DRGs 820, 821, and 822 (Lymphoma and Leukemia with Major Procedure with MCC, with CC, and without CC/MCC, respectively), MS–DRGs 826, 827, and 828 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major Procedure with MCC, with CC, and without CC/MCC, respectively), and MS–DRGs 829 and 830 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other Procedure with CC/MCC and without CC/MCC, respectively) in MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms).

During our review, we also noted that ICD–10–PCS procedure code 0DB64Z3 (Excision of stomach, percutaneous endoscopic approach, vertical (sleeve)), which is clinically similar to ICD–10–PCS codes 0DB64ZZ and 0DB64ZX, is designated as an O.R. procedure assigned to the same MS–DRGs as we are proposing for ICD–10–PCS codes 0DB64ZZ and 0DB64ZX, as well as to MS–DRG 264 (Other Circulatory System O.R. Procedures) in MDC 05 (Diseases and Disorders of the Circulatory System); MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries, with MCC, with CC, and without CC/MCC, respectively) in MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs); and MS–DRGs 957, 958, and 959 (Other O.R. procedures for multiple significant trauma, with MCC, with CC, and without CC/MCC, respectively) in MDC 24 (Multiple Significant Trauma). Our clinical advisors believe that principal diagnoses in MDCs 05 and 21 are typically not indications for procedures describing percutaneous endoscopic excision of stomach and that ICD–10–PCS procedure code 0DB64Z3 should be assigned to the same MS–DRGs as ICD–10–PCS codes 0DB64ZZ and 0DB64ZX. We examined claims data from the September 2019 update of the FY 2019 MedPAR file to determine if there were any cases that reported 0DB64Z3 and were assigned to MDC 05, MDC 21, or MDC 24. The following table shows our findings:

MDC 05 and MDC 21: Cases Reporting Procedures Describing Percutaneous Endoscopic Excision of Stomach, Vertical (Sleeve)

MDC	MS-DRG		Number of Cases	Average Length of Stay	Average Costs
05	264	All Cases	9,666	9.1	$22,637
		0DB64Z3	6	9.5	$32,579
21	907	All Cases	9,622	9.6	$28,026
		0DB64Z3	2	3.0	$14,281
	908	All Cases	8,498	5.2	$14,647
		0DB64Z3	5	1.2	$11,788
	909	All Cases	2,797	3	$10,073
		0DB64Z3	1	2.0	$6,887

We found zero cases in MS–DRGs 957, 958, and 959 reporting 0DB64Z3 and a principal diagnosis in MDC 24 (Multiple Significant Trauma). Our analysis demonstrates that diagnoses assigned to MDC 05, MDC 21, and MDC 24 are not typically corrected surgically by percutaneous endoscopic vertical (sleeve) gastrectomy given the small number of cases reporting this procedure in these MDCs. Our clinical advisors believe procedure codes describing the percutaneous endoscopic excision of stomach should have the same MDC assignments in the ICD–10 MS–DRGs Version 38 for coherence. Therefore, we are proposing to remove the assignments of code 0DB64Z3 from MS–DRG 264 (Other Circulatory System O.R. Procedures) in MDC 05 (Diseases and Disorders of the Circulatory System); MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries, with MCC, with CC, and without CC/MCC, respectively) in MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs); and MS–DRGs 957, 958, and 959 (Other O.R. procedures for multiple significant trauma, with MCC, with CC, and without CC/MCC, respectively) in MDC 24 (Multiple Significant Trauma).

Lastly, while we were reviewing this request, we noted inconsistencies in how procedures involving the excision of stomach are designated. Excision of stomach codes differ by approach and qualifier. ICD–10–PCS procedure codes describing excision of stomach with similar approaches have been assigned

different attributes in terms of designation as an O.R. or Non-O.R. procedure. We identified the following five related codes:

ICD-10-PCS Code	Code Description
0DB63Z3	Excision of stomach, percutaneous approach, vertical
0DB63ZZ	Excision of stomach, percutaneous approach
0DB67Z3	Excision of stomach, via natural or artificial opening, vertical
0DB67ZZ	Excision of stomach, via natural or artificial opening
0DB68Z3	Excision of stomach, via natural or artificial opening endoscopic, vertical

In the ICD–10 MS–DRGs Version 37, these ICD–10–PCS codes are currently recognized as O.R. procedures for purposes of MS–DRG assignment, while similar excision of stomach procedure codes with the same approach but different qualifiers are recognized as Non-O.R. procedures. Our clinical advisors indicated that these procedures are not surgical in nature and do not require an incision. Therefore, we are proposing to remove ICD–10–PCS procedure codes 0DB63Z3, 0DB63ZZ, 0DB67Z3, 0DB67ZZ, and 0DB68Z3 from the FY 2021 ICD–10 MS–DRG Version 38 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures. Under this proposal, these procedures would no longer impact MS–DRG assignment.

(4) Percutaneous Endoscopic Drainage

One requestor identified six ICD–10–PCS procedure codes that describe procedures involving laparoscopic drainage of peritoneum, peritoneal cavity, and gallbladder that the requestor stated are currently not recognized as O.R. procedures for purposes of MS–DRG assignment. The six procedure codes are listed in the following table:

ICD-10-PCS Code	Code Description
0D9W4ZZ	Drainage of peritoneum, percutaneous endoscopic approach
0D9W40Z	Drainage of peritoneum with drainage device, percutaneous endoscopic approach
0W9G4ZZ	Drainage of peritoneal cavity, percutaneous endoscopic approach
0W9G40Z	Drainage of peritoneal cavity with drainage device, percutaneous endoscopic approach
0F944ZZ	Drainage of gallbladder, percutaneous endoscopic approach
0F9440Z	Drainage of gallbladder with drainage device, percutaneous endoscopic approach

The requestor stated these procedures would commonly be performed under general anesthesia and require the resources of an operating room. The requestor also noted that similar procedures such as percutaneous endoscopic inspection of gallbladder, percutaneous endoscopic excision of peritoneum and percutaneous endoscopic extirpation of matter from peritoneal cavity are currently classified as O.R. procedures in Version 37 of the ICD–10 MS–DRGs and that the six listed procedure codes should be designated as O.R. procedures due to comparable costs and resource use.

We agree with the requestor that the six ICD–10–PCS procedure codes listed in the table typically require the resources of an operating room. Therefore, to the FY 2021 ICD–10 MS–DRG Version 38 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index, we are proposing to add codes 0D9W4ZZ and 0D9W40Z as O.R. procedures assigned to MS–DRGs 356, 357, and 358 (Other Digestive System O.R. Procedures, with MCC, with CC, and without CC/MCC, respectively) in MDC 06 (Diseases and Disorders of the Digestive System); and MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively) in MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs). We are also proposing to add codes 0W9G4ZZ and 0W9G40Z as O.R. procedures assigned to MS–DRGs 356, 357, and 358 (Other Digestive System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 06 (Diseases and Disorders of the Digestive System); MS–DRGs 420, 421, and 422 (Hepatobiliary Diagnostic Procedures, with MCC, with CC, and without CC/MCC, respectively) in MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas); MS–DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures, with MCC, with CC, and without CC/MCC, respectively) in MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract); MS–DRGs 749 and 750 (Other Female Reproductive System Procedures with and without CC/MCC, respectively) in MDC 13 (Diseases and Disorders of the Female Reproductive System); MS–DRGs 802, 803, and 804 (Other O.R. Procedures of the Blood and Blood Forming Organs, with MCC, with CC, and without CC/MCC, respectively) in MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs, Immunologic Disorders); MS–DRGs 820, 821, and 822 (Lymphoma and Leukemia with Major Procedure with MCC, with CC, and without CC/MCC, respectively) and MS–DRGs 826, 827, and 828 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major Procedure with MCC, with CC, and without CC/MCC, respectively) in MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms); and MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively) in MDC 21 (Injuries, Poisonings and Toxic

Effects of Drugs). Lastly, we are proposing to add codes 0F944ZZ and 0F9440Z as O.R. procedures assigned to MS–DRGs 408, 409, and 410 (Biliary Tract Procedures Except Only Cholecystectomy with or without C.D.E., with MCC, with CC, and without CC/MCC, respectively) in MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas).

We identified related ICD–10–PCS procedure code 0F944ZX (Drainage of gallbladder, percutaneous endoscopic approach, diagnostic) that is also currently not recognized as an O.R. procedure for purposes of MS–DRG assignment. Our clinical advisors believe that similar to the six procedure codes submitted by the requester, this procedure typically requires the resources of an operating room and should have the same attributes in Version 38 for coherence. Therefore, we are proposing to add code 0F944ZX as an O.R. procedure assigned to MS–DRGs 420, 421 and 422 (Hepatobiliary Diagnostic Procedures, with MCC, with CC, and without CC/MCC, respectively) in MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas) to the FY 2021 ICD–10 MS–DRG Version 38 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index.

During our review, we also identified the related ICD–10–PCS procedure codes 0F940ZZ (Drainage of gallbladder, open approach), 0F940ZX (Drainage of gallbladder, open approach, diagnostic) and 0F9400Z (Drainage of gallbladder with drainage device, open approach). Our analysis found that the ICD–10–PCS codes describing drainage of gallbladder have dissimilar MDC assignments. Procedure codes 0F940ZZ and 0F940ZX are currently assigned to MS–DRGs 356, 357, and 358 (Other Digestive System O.R. Procedures, with MCC, with CC, and without CC/MCC, respectively) in MDC 06 (Diseases and Disorders of the Digestive System) and MS–DRGs 408, 409, and 410 (Biliary Tract Procedures Except Only Cholecystectomy with or without C.D.E. with MCC, with CC, and without CC/MCC, respectively) in MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas). However, ICD–10–PCS procedure code 0F9400Z is currently assigned to MS–DRGs 408, 409, and 410 (Biliary Tract Procedures Except Only Cholecystectomy with or without C.D.E. with MCC, with CC, and without CC/MCC, respectively) in MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas) alone. Our clinical advisors believe that principal diagnoses in MDC 06 are typically not indications for procedures describing the drainage of gallbladder. We examined claims data from the September 2019 update of the FY 2019 MedPAR file to determine if there were any cases that reported procedure codes 0F940ZZ or 0F940ZX and were assigned to MDC 06. We found zero cases in MS–DRGs 356, 357, and 358 reporting code 0F944ZZ or 0F940ZX and a principal diagnosis in MDC 06 (Diseases and Disorders of the Digestive System), demonstrating that diagnoses in MDC 06 are not typically corrected surgically by drainage of the gallbladder. Our clinical advisors believe procedure codes describing the drainage of gallbladder should have the same MDC assignments in Version 38 for coherence. Therefore, we are proposing to remove procedure codes 0F940ZZ and 0F940ZX from MS–DRGs 356, 357, and 358 in MDC 06 (Diseases and Disorders of the Digestive System).

Our further analysis of this request identified the nine ICD–10–PCS codes in the following table describing drainage of the peritoneum, peritoneal cavity, or gallbladder:

ICD-10-PCS Code	Code Description
0D9W00Z	Drainage of peritoneum with drainage device, open approach
0D9W0ZX	Drainage of peritoneum, open approach, diagnostic
0D9W0ZZ	Drainage of peritoneum, open approach
0D9W4ZX	Drainage of peritoneum, percutaneous endoscopic approach, diagnostic
0W9G00Z	Drainage of peritoneal cavity with drainage device, open approach
0W9G0ZZ	Drainage of peritoneal cavity, open approach
0F9400Z	Drainage of gallbladder with drainage device, open approach
0F940ZZ	Drainage of gallbladder, open approach
0F940ZX	Drainage of gallbladder, open approach, diagnostic

We note that these procedures are currently classified as extensive O.R. procedures. Our clinical advisors have noted that treatment practices have shifted since the initial O.R procedure designations. Our clinical advisors believe that, given the similarity in factors such as complexity, resource utilization, and requirement for anesthesia administration between procedures describing the drainage of the peritoneum, peritoneal cavity, and gallbladder, it would be more appropriate to designate these nine ICD–10–PCS codes as non-extensive O.R. procedures. Therefore, we are also proposing to change the designation of ICD–10–PCS codes 0D9W00Z, 0D9W0ZX, 0D9W0ZZ, 0D9W4ZX, 0W9G00Z, 0W9G0ZZ, 0F9400Z, 0F940ZZ, and 0F940ZX from extensive O.R. procedures to non-extensive O.R. procedures for FY 2021.

(5) Control of Bleeding

One requestor identified ICD–10–PCS procedure code 0W3G0ZZ (Control bleeding in peritoneal cavity, open approach) that describes a procedure in which the bleeding source within the peritoneal cavity is controlled by cautery, clips, and/or suture through an open abdominal incision with direct visualization of the surgical site, that the requestor stated requires the resources of an operating room and general anesthesia but is currently not recognized as an O.R. procedure for purposes of MS–DRG assignment. The requestor also noted that ICD–10–PCS procedure codes 0W3F0ZZ (Control bleeding in abdominal wall, open approach), 0W3H0ZZ (Control bleeding in retroperitoneum, open approach), and 0W3J0ZZ (Control bleeding in pelvic cavity, open approach) describe procedures to control bleeding in

various anatomic sites and are currently classified as O.R. procedures.

We agree with the requestor that it would be clinically appropriate to redesignate procedure code 0W3G0ZZ as an O.R. procedure consistent with procedure codes 0W3F0ZZ, 0W3H0ZZ and 0W3J0ZZ, that also describe procedures performed to control bleeding and are designated as O.R. procedures. Therefore, we are proposing to add procedure code 0W3G0ZZ to the FY 2021 ICD–10 MS–DRG Version 38 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as an O.R. procedure assigned to MS–DRG 264 (Other Circulatory O.R. Procedures) in MDC 05 (Diseases and Disorders of the Circulatory System); MS–DRGs 356, 357, and 358 (Other Digestive System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 06 (Diseases and Disorders of the Digestive System); MS–DRGs 423, 424, and 425 (Other Hepatobiliary or Pancreas O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas); MS–DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract); MS–DRGs 820, 821, and 822 (Lymphoma and Leukemia with Major O.R. Procedure with MCC, with CC, and without CC/MCC, respectively), MS–DRGs 826, 827, and 828 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedure with MCC, with CC, and without CC/MCC, respectively), and MS–DRGs 829 and 830 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other Procedure with and without CC/MCC, respectively) in MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms); MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with and without CC/MCC, respectively) in MDC 21 ((Injuries, Poisonings and Toxic Effects of Drugs); MS–DRGs 957, 958, and 959 (Other O.R. Procedures for Multiple Significant Trauma, with MCC, with CC, and without CC/MCC, respectively) in MDC 24 (Multiple Significant Trauma) and to MS–DRGs 981, 982 and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively).

(6) Inspection of Penis

One requestor stated that ICD–10–PCS procedure code 0VJS0ZZ (Inspection of penis, open approach) is currently not recognized as an O.R. procedure for purposes of MS–DRG assignment. The requestor noted that there are circumstances that warrant inpatient admission for open exploration of the penis, such as to rule out penile fracture and extravasation due to trauma. The requestor stated their belief that because this procedure involves an open incision for exploration of penile structures and utilizes general anesthesia in the operating room, it would be appropriately classified as an O.R. procedure. We agree with the requestor that ICD–10–PCS code 0VJS0ZZ typically requires the resources of an operating room. Therefore, we are proposing to add ICD–10–PCS procedure code 0VJS0ZZ to the FY 2021 ICD–10 MS–DRG Version 38 Definitions Manual in Appendix E—Operating Room procedures and procedure code/MS–DRG Index as an O.R. procedure assigned to MS–DRGs 709 (Penis Procedures with CC/MCC) and 710 (Penis Procedures without CC/MCC) in MDC 12 (Diseases and Disorders of the Male Reproductive System).

12. Proposed Changes to the MS–DRG Diagnosis Codes for FY 2021

a. Background of the CC List and the CC Exclusions List

Under the IPPS MS–DRG classification system, we have developed a standard list of diagnoses that are considered CCs. Historically, we developed this list using physician panels that classified each diagnosis code based on whether the diagnosis, when present as a secondary condition, would be considered a substantial complication or comorbidity. A substantial complication or comorbidity was defined as a condition that, because of its presence with a specific principal diagnosis, would cause an increase in the length-of-stay by at least 1 day in at least 75 percent of the patients. However, depending on the principal diagnosis of the patient, some diagnoses on the basic list of complications and comorbidities may be excluded if they are closely related to the principal diagnosis. In FY 2008, we evaluated each diagnosis code to determine its impact on resource use and to determine the most appropriate CC subclassification (non-CC, CC, or MCC) assignment. We refer readers to sections II.D.2. and 3. of the preamble of the FY 2008 IPPS final rule with comment period for a discussion of the refinement of CCs in relation to the MS–DRGs we adopted for FY 2008 (72 FR 47152 through 47171).

b. Overview of Comprehensive CC/MCC Analysis

In the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159), we described our process for establishing three different levels of CC severity into which we would subdivide the diagnosis codes. The categorization of diagnoses as a MCC, a CC, or a non-CC was accomplished using an iterative approach in which each diagnosis was evaluated to determine the extent to which its presence as a secondary diagnosis resulted in increased hospital resource use. We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159) for a complete discussion of our approach. Since the comprehensive analysis was completed for FY 2008, we have evaluated diagnosis codes individually when receiving requests to change the severity level of specific diagnosis codes.

We noted in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235) that with the transition to ICD–10–CM and the significant changes that have occurred to diagnosis codes since the FY 2008 review, we believed it was necessary to conduct a comprehensive analysis once again. Based on this analysis, we proposed changes to the severity level designations for 1,492 ICD–10–CM diagnosis codes and invited public comments on those proposals. As summarized in the FY 2020 IPPS/LTCH PPS final rule, many commenters expressed concern with the proposed severity level designation changes overall and recommended that CMS conduct further analysis prior to finalizing any proposals. After careful consideration of the public comments we received, as discussed further in the FY 2020 final rule, we generally did not finalize our proposed changes to the severity designations for the ICD–10–CM diagnosis codes, other than the changes to the severity level designations for the diagnosis codes in category Z16—(Resistance to antimicrobial drugs) from a non-CC to a CC. We stated that postponing adoption of the proposed comprehensive changes in the severity level designations would allow further opportunity to provide additional background to the public on the methodology utilized and clinical rationale applied across diagnostic categories to assist the public in its review. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42150 through 42152) for a complete discussion of our response to public comments regarding the proposed severity level designation changes for FY 2020.

c. Guiding Principles for Making Changes to Severity Levels

To provide the public with more information on the CC/MCC comprehensive analysis discussed in the FY 2020 IPPS/LTCH PPS proposed and final rules, CMS hosted a listening session on October 8, 2019. The listening session included a review of the methodology to measure the impact on resource use. It also provided an opportunity for CMS to receive public input on this analysis and to address any questions in order to assist the public in formulating written comments on the current severity level designations for consideration in the FY 2021 rulemaking. We refer readers to *https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/PodcastAndTranscripts.html* for the transcript and audio file of the listening session. We also refer readers to *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html* for the supplementary file containing the data describing the impact on resource use of specific ICD–10–CM diagnosis codes when reported as a secondary diagnosis that was made available for the listening session.

Following the listening session, we further considered the public comments received and reconvened an internal workgroup comprised of clinicians, consultants, coding specialists and other policy analysts to identify guiding principles to apply in evaluating whether changes to the severity level designations of diagnoses are needed and to ensure the severity designations proposed appropriately reflect resource use based on review of the claims data, as well as consideration of relevant clinical factors (for example, the clinical nature of each of the secondary diagnoses and the severity level of clinically similar diagnoses) and improve the overall accuracy of the IPPS payments. Our goal was to develop a set of guiding principles that, when applied, could assist in determining whether the presence of the specified secondary diagnosis would lead to increased hospital resource use in most instances. The workgroup identified the following nine guiding principles as meaningful indicators of expected resource use by a secondary diagnosis:

- Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and debility.
- Denotes organ system instability or failure.
- Involves a chronic illness with susceptibility to exacerbations or abrupt decline.
- Serves as a marker for advanced disease states across multiple different comorbid conditions.
- Reflects systemic impact.
- Post-operative condition/complication impacting recovery.
- Typically requires higher level of care (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay).
- Impedes patient cooperation and/or management of care.
- Recent (last 10 years) change in best practice, or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use.

Using a combination of mathematical analysis of claims data as discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235) and the application of these guiding principles, we plan to continue a comprehensive CC/MCC analysis and present the findings and proposals in future rulemaking. We are inviting public comments regarding these guiding principles, as well as other possible ways we can incorporate meaningful indicators of clinical severity. When providing additional feedback or comments, we encourage the public to provide a detailed explanation of how applying a suggested concept or principle would ensure that the severity designation appropriately reflects resource use for any diagnosis code.

d. Proposed Additions and Deletions to the Diagnosis Code Severity Levels for FY 2021

The following tables identify the proposed additions and deletions to the diagnosis code MCC severity levels list and the proposed additions and deletions to the diagnosis code CC severity levels list for FY 2021 and are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

Table 6I.1—Proposed Additions to the MCC List—FY 2021;

Table 6I.2— Proposed Deletions to the MCC List—FY 2021;

Table 6J.1— Proposed Additions to the CC List—FY 2021; and

Table 6J.2— Proposed Deletions to the CC List—FY 2021.

e. Proposed CC Exclusions List for FY 2021

In the September 1, 1987 final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPER logic so that certain diagnoses included on the standard list of CCs would not be considered valid CCs in combination with a particular principal diagnosis. We created the CC Exclusions List for the following reasons: (1) To preclude coding of CCs for closely related conditions; (2) to preclude duplicative or inconsistent coding from being treated as CCs; and (3) to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair.

In the May 19, 1987 proposed notice (52 FR 18877) and the September 1, 1987 final notice (52 FR 33154), we explained that the excluded secondary diagnoses were established using the following five principles:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another;
- Specific and nonspecific (that is, not otherwise specified (NOS)) diagnosis codes for the same condition should not be considered CCs for one another;
- Codes for the same condition that cannot coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another;
- Codes for the same condition in anatomically proximal sites should not be considered CCs for one another; and
- Closely related conditions should not be considered CCs for one another.

The creation of the CC Exclusions List was a major project involving hundreds of codes. We have continued to review the remaining CCs to identify additional exclusions and to remove diagnoses from the master list that have been shown not to meet the definition of a CC. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50541 through 50544) for detailed information regarding revisions that were made to the CC and CC Exclusion Lists under the ICD–9–CM MS–DRGs.

The ICD–10 MS–DRGs Version 37 CC Exclusion List is included as Appendix C in the ICD–10 MS–DRG Definitions Manual, which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html*, and includes two lists identified as Part 1 and Part 2. Part 1 is the list of all diagnosis codes that are defined as a CC or MCC when reported as a secondary diagnosis. For all diagnosis codes on the list, a link is provided to a collection of diagnosis codes which, when used as the principal diagnosis, would cause the

CC or MCC diagnosis to be considered as a non-CC. Part 2 is the list of diagnosis codes designated as a MCC only for patients discharged alive; otherwise, they are assigned as a non-CC.

We received a request to consider removing diagnosis codes describing any type of stroke that is designated as a MCC in the code range I60.00 through I63.9 from the CC Exclusion list when a principal diagnosis of diabetes in the code range E08.00 through E13 is reported. According to the requestor, acute strokes and chronic diabetes are two distinct conditions, therefore a stroke that occurs during an admission for an underlying diabetic condition should not be excluded from acting as a MCC. The requestor provided an example of a patient with type 2 diabetes who was admitted for treatment of infected foot ulcers and then experienced a stroke prior to discharge, resulting in assignment to MS–DRG 639 (Diabetes without CC/MCC). The requestor asserted the more appropriate assignment is MS–DRG 637 (Diabetes with MCC), which they stated more appropriately reflects severity of illness and resources involved in the treatment of an acute stroke. In another example provided by the requestor, a patient with type 2 diabetes and osteomyelitis underwent a left below the knee amputation and experienced a stroke before discharge, resulting in assignment to MS–DRG 617 (Amputation of Lower Limb for Endocrine, Nutritional, and Metabolic Diseases with CC). The requestor asserted the more appropriate assignment is MS–DRG 616 (Amputation of Lower Limb for Endocrine, Nutritional, and Metabolic Diseases with MCC), which they stated more appropriately reflects severity of illness and resources involved in the treatment an acute stroke.

Our clinical advisors agree that acute strokes and chronic diabetes are two distinct conditions and a case reporting a secondary diagnosis of a stroke in the code range I60.00 through I63.9 should not be excluded from acting as a MCC when reported with a principal diagnosis of diabetes in the code range E08.00 through E13.9.

We analyzed claims data from the September 2019 update of the FY 2019 MedPAR file for cases reporting a principal diagnosis of diabetes in the code range E08.00 through E13.9 with a secondary diagnosis of a stroke in the code range I60.00 through I63.9. We refer the reader to table 6P.3a for a detailed list of the diagnosis codes describing diabetes that were analyzed and table 6P.3b for a detailed list of the diagnosis codes describing a stroke that were analyzed and that are also designated as a MCC in this code range. We found a total of 1,109 cases across 40 MS–DRGs with an average length of stay of 10.1 days and average costs of $24,672 reporting a principal diagnosis of diabetes with a secondary diagnosis of a stroke that was excluded from acting as a MCC. Of those 1,109 cases, we identified 161 cases that would result in assignment to the higher severity level ''with MCC'' MS–DRG if the diagnosis of stroke was no longer excluded from acting as a MCC. The remaining 948 cases would maintain their existing MS–DRG assignment since they were either already grouped to the highest MCC severity level based on another diagnosis code that is designated as a MCC or they were assigned to one of the Pre-MDC MS–DRGs. We refer the reader to table 6P.4a for the detailed analysis.

Based on the advice of our clinical advisors, for FY 2021, we are proposing to remove the diagnosis codes describing stroke in the code range I60.00 through I63.9 that are designated as a MCC from the list of CC Exclusions when reported with a principal diagnosis of diabetes in the code range E08.00 through E13.9 from the ICD–10 MS–DRGs Version 38 CC Exclusion List as reflected in Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2021 and Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2021.

We are proposing additional changes to the ICD–10 MS–DRGs Version 38 CC Exclusion List based on the diagnosis and procedure code updates as discussed in section II.D.13. of this FY 2021 IPPS/LTCH PPS proposed rule. Therefore, we have developed Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2021; Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2021; Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2021; and Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2021. For Table 6G.1, each secondary diagnosis code proposed for addition to the CC Exclusion List is shown with an asterisk and the principal diagnoses proposed to exclude the secondary diagnosis code are provided in the indented column immediately following it. For Table 6G.2, each of the principal diagnosis codes for which there is a CC exclusion is shown with an asterisk and the conditions proposed for addition to the CC Exclusion List that will not count as a CC are provided in an indented column immediately following the affected principal diagnosis. For Table 6H.1, each secondary diagnosis code proposed for deletion from the CC Exclusion List is shown with an asterisk followed by the principal diagnosis codes that currently exclude it. For Table 6H.2, each of the principal diagnosis codes is shown with an asterisk and the proposed deletions to the CC Exclusions List are provided in an indented column immediately following the affected principal diagnosis. Tables 6G.1., 6G.2., 6H.1., and 6H.2. associated with this proposed rule are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

13. Proposed Changes to the ICD–10–CM and ICD–10–PCS Coding Systems

To identify new, revised and deleted diagnosis and procedure codes, for FY 2021, we have developed Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, and Table 6E.—Revised Diagnosis Code Titles for this proposed rule.

These tables are not published in the Addendum to this proposed rule, but are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as described in section VI. of the Addendum to this proposed rule. As discussed in section II.D.16. of the preamble of this proposed rule, the code titles are adopted as part of the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting process. Therefore, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules.

We are proposing the MDC and MS–DRG assignments for the new diagnosis codes and procedure codes as set forth in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes. In addition, the proposed severity level designations for the new diagnosis codes are set forth in Table 6A. and the proposed O.R. status for the new procedure codes are set forth in Table 6B.

We are making available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* the following tables associated with this proposed rule:

- Table 6A.—New Diagnosis Codes–FY 2021;

- Table 6B.—New Procedure Codes–FY 2021;
- Table 6C.—Invalid Diagnosis Codes–FY 2021;
- Table 6E.—Revised Diagnosis Code Titles–FY 2021;
- Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List–FY 2021;
- Table 6G.2.— Proposed Principal Diagnosis Order Additions to the CC Exclusions List–FY 2021;
- Table 6H.1.— Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List–FY 2021;
- Table 6H.2.— Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2021;
- Table 6I.1.— Proposed Additions to the MCC List–FY 2021;
- Table 6I.2.– Proposed Deletions to the MCC List–FY 2021;
- Table 6J.1.— Proposed Additions to the CC List–FY 2021; and
- Table 6J.2.— Proposed Deletions to the CC List –FY 2021.

14. Proposed Changes to the Medicare Code Editor (MCE)

The Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, procedure(s), and demographic information are entered into the Medicare claims processing systems and are subjected to a series of automated screens. The MCE screens are designed to identify cases that require further review before classification into an MS–DRG.

As discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42156), we made available the FY 2020 ICD–10 MCE Version 37 manual file. The manual contains the definitions of the Medicare code edits, including a description of each coding edit with the corresponding diagnosis and procedure code edit lists. The link to this MCE manual file, along with the link to the mainframe and computer software for the MCE Version 37 (and ICD–10 MS–DRGs) are posted on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS–DRG-Classifications-and-Software*.

For this FY 2021 IPPS/LTCH PPS proposed rule, we address the MCE requests we received by the November 1, 2019 deadline. We also discuss the proposals we are making based on our internal review and analysis.

a. Age Conflict Edit

In the MCE, the Age conflict edit exists to detect inconsistencies between a patient's age and any diagnosis on the patient's record; for example, a 5-year-old patient with benign prostatic hypertrophy or a 78-year-old patient coded with a delivery. In these cases, the diagnosis is clinically and virtually impossible for a patient of the stated age. Therefore, either the diagnosis or the age is presumed to be incorrect. Currently, in the MCE, the following four age diagnosis categories appear under the Age conflict edit and are listed in the manual and written in the software program:

- Perinatal/Newborn—Age 0 years only; a subset of diagnoses which will only occur during the perinatal or newborn period of age 0 (for example, tetanus neonatorum, health examination for newborn under 8 days old).
- Pediatric—Age is 0–17 years inclusive (for example, Reye's syndrome, routine child health exam).
- Maternity—Age range is 9–64 years inclusive (for example, diabetes in pregnancy, antepartum pulmonary complication).
- Adult—Age range is 15–124 years inclusive (for example, senile delirium, mature cataract).

(1) Maternity Diagnoses

Under the ICD–10 MCE, the Maternity diagnoses category for the Age conflict edit considers the age range of 9 to 64 years inclusive. For that reason, the diagnosis codes on this Age conflict edit list would be expected to apply to conditions or disorders specific to that age group only.

As discussed in section II.D.13. of the preamble of this proposed rule, Table 6A.—New Diagnosis Codes, lists the diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2020. We are proposing to add the following new ICD–10–CM diagnosis codes listed in this section of this rule to the Maternity diagnoses category code list under the Age conflict edit.

ICD-10-CM Code	Code Description
O34.218	Maternal care for other type scar from previous cesarean delivery
O34.22	Maternal care for cesarean scar defect (isthmocele)
O99.891	Other specified diseases and conditions complicating pregnancy
O99.892	Other specified diseases and conditions complicating childbirth
O99.893	Other specified diseases and conditions complicating puerperium

In addition, as discussed in section II.D.13. of the preamble of this proposed rule, Table 6C.—Invalid Diagnosis Codes, lists the diagnosis codes that are no longer effective October 1, 2020. Included in this table is ICD–10–CM diagnosis code O99.89 (Other specified diseases and conditions complicating pregnancy, childbirth and the puerperium) which is currently listed on the Maternity diagnoses category code list under the Age Conflict edit. We are proposing to remove this code from the Maternity diagnoses category code list.

(2) Adult Diagnoses

Under the ICD–10 MCE, the Adult diagnoses category for the Age conflict edit considers the age range of 15 to 124 years inclusive. For that reason, the diagnosis codes on this Age conflict edit list would be expected to apply to conditions or disorders specific to that age group only.

As discussed in section II.D.13. of the preamble of this proposed rule, Table 6A.—New Diagnosis Codes, lists the diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2020. We are proposing to add the following new ICD–10–CM diagnosis codes to the Adult diagnoses category code list under the Age conflict edit.

ICD-10-CM Code	Code Description
M80.0AXA	Age-related osteoporosis with current pathological fracture, other site, initial encounter for fracture
M80.0AXD	Age-related osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with routine healing
M80.0AXG	Age-related osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with delayed healing
M80.0AXK	Age-related osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with nonunion
M80.0AXP	Age-related osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with malunion
M80.0AXS	Age-related osteoporosis with current pathological fracture, other site, sequela

b. Sex Conflict Edit

In the MCE, the Sex conflict edit detects inconsistencies between a patient's sex and any diagnosis or procedure on the patient's record; for example, a male patient with cervical cancer (diagnosis) or a female patient with a prostatectomy (procedure). In both instances, the indicated diagnosis or the procedure conflicts with the stated sex of the patient. Therefore, the patient's diagnosis, procedure, or sex is presumed to be incorrect.

(1) Diagnoses for Females Only Edit

As discussed in section II.D.13. of the preamble of this proposed rule, Table 6A.—New Diagnosis Codes, lists the new diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2020. We are proposing to add the following new ICD–10–CM diagnosis codes listed in this section of this rule to the edit code list for the Diagnoses for Females Only edit.

ICD-10-CM Code	Code Description
O34.218	Maternal care for other type scar from previous cesarean delivery
O34.22	Maternal care for cesarean scar defect (isthmocele)
O99.891	Other specified diseases and conditions complicating pregnancy
O99.892	Other specified diseases and conditions complicating childbirth
O99.893	Other specified diseases and conditions complicating puerperium

In addition, as discussed in section II.D.13. of the preamble of this proposed rule, Table 6C.—Invalid Diagnosis Codes, lists the diagnosis codes that are no longer effective October 1, 2020. Included in this table are ICD–10–CM diagnosis code O99.89 (Other specified diseases and conditions complicating pregnancy, childbirth and the puerperium) and ICD–10–CM diagnosis code Q51.20 (Other doubling of uterus, unspecified) which are currently listed on the Diagnoses for Females Only edit code list. We are proposing to delete these codes from the Diagnoses for Females Only edit code list.

(2) Procedures for Females Only Edit

As discussed in section II.D.13. of the preamble of this proposed rule, Table 6B.—New Procedure Codes, lists the new procedure codes that have been approved to date which will be effective with discharges on and after October 1, 2020. We are proposing to add the following new ICD–10–PCS procedure codes listed in this section of this rule to the edit code list for the Procedures for Females Only edit.

ICD-10-PCS Code	Code Description
DU10B6Z	Low dose rate (LDR) brachytherapy of ovary using Cesium 131 (Cs-131)
DU11B6Z	Low dose rate (LDR) brachytherapy of cervix using Cesium 131 (Cs-131)
DU12B6Z	Low dose rate (LDR) brachytherapy of uterus using Cesium 131 (Cs-131)

(3) Procedures for Males Only

As discussed in section II.D.13. of the preamble of this proposed rule, Table 6B.—New Procedure Codes, lists the new procedure codes that have been approved to date which will be effective with discharges on and after October 1, 2020. We are proposing to add the following new ICD–10–PCS procedure

codes listed in this section of this rule to the edit code list for the Procedures for Males Only edit.

ICD-10-PCS Code	Code Description
DV10B6Z	Low dose rate (LDR) brachytherapy of prostate using Cesium 131 (Cs-131)
DV11B6Z	Low dose rate (LDR) brachytherapy of testis using Cesium 131 (Cs-131)

c. Manifestation Code as Principal Diagnosis Edit

In the ICD–10–CM classification system, manifestation codes describe the manifestation of an underlying disease, not the disease itself, and therefore should not be used as a principal diagnosis.

As discussed in section II.D.13. of the preamble of this proposed rule, Table 6A—New Diagnosis Codes, lists the new diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2020. We are proposing to add the following new ICD–10–CM diagnosis codes listed in this section of this rule to the edit code list for the Manifestation Codes Not Allowed as Principal Diagnosis edit code list because these codes are describing the manifestation of an underlying disease and not the disease itself.

ICD-10-CM Code	Code Description
D72.18	Eosinophilia in diseases classified elsewhere
D84.81	Immunodeficiency due to conditions classified elsewhere
J84.170	Interstitial lung disease with progressive fibrotic phenotype in diseases classified elsewhere
J84.178	Other interstitial pulmonary diseases with fibrosis in diseases classified elsewhere

In addition, as discussed in section II.D.13. of the preamble of this proposed rule, Table 6C.—Invalid Diagnosis Codes, lists the diagnosis codes that are no longer effective October 1, 2020. Included in this table is ICD–10–CM diagnosis code J84.17 (Other interstitial pulmonary diseases with fibrosis in diseases classified elsewhere) which is currently listed on the Manifestation Codes Not Allowed as Principal Diagnosis edit code list. We are proposing to delete this code from the Manifestation Codes Not Allowed as Principal Diagnosis edit code list.

d. Unacceptable Principal Diagnosis Edit

In the MCE, there are select codes that describe a circumstance which influences an individual's health status but does not actually describe a current illness or injury. There also are codes that are not specific manifestations but may be due to an underlying cause. These codes are considered unacceptable as a principal diagnosis. In limited situations, there are a few codes on the MCE Unacceptable Principal Diagnosis edit code list that are considered ''acceptable'' when a specified secondary diagnosis is also coded and reported on the claim.

As discussed in Section II.D.13. of the preamble of this proposed rule, Table 6A.—New Diagnosis Codes, lists the new diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2020. We are proposing to add the following new ICD–10–CM diagnosis codes listed in this section of this rule to the Unacceptable Principal Diagnosis edit code list.

ICD-10-CM Code	Code Description
D89.831	Cytokine release syndrome, grade 1
D89.832	Cytokine release syndrome, grade 2
D89.833	Cytokine release syndrome, grade 3
D89.834	Cytokine release syndrome, grade 4
D89.835	Cytokine release syndrome, grade 5
D89.839	Cytokine release syndrome, grade unspecified
K74.00	Hepatic fibrosis, unspecified
K74.01	Hepatic fibrosis, early fibrosis
K74.02	Hepatic fibrosis, advanced fibrosis
T40.415A	Adverse effect of fentanyl or fentanyl analogs, initial encounter
T40.415D	Adverse effect of fentanyl or fentanyl analogs, subsequent encounter
T40.415S	Adverse effect of fentanyl or fentanyl analogs, sequela
T40.416A	Underdosing of fentanyl or fentanyl analogs, initial encounter
T40.416D	Underdosing of fentanyl or fentanyl analogs, subsequent encounter
T40.416S	Underdosing of fentanyl or fentanyl analogs, sequela
T40.425A	Adverse effect of tramadol, initial encounter
T40.425D	Adverse effect of tramadol, subsequent encounter
T40.425S	Adverse effect of tramadol, sequela
T40.426A	Underdosing of tramadol, initial encounter
T40.426D	Underdosing of tramadol, subsequent encounter
T40.426S	Underdosing of tramadol, sequela
T40.495A	Adverse effect of other synthetic narcotics, initial encounter
T40.495D	Adverse effect of other synthetic narcotics, subsequent encounter
T40.495S	Adverse effect of other synthetic narcotics, sequela
T40.496A	Underdosing of other synthetic narcotics, initial encounter
T40.496D	Underdosing of other synthetic narcotics, subsequent encounter
T40.496S	Underdosing of other synthetic narcotics, sequela
Z03.821	Encounter for observation for suspected ingested foreign body ruled out
Z03.822	Encounter for observation for suspected aspirated (inhaled) foreign body ruled out
Z03.823	Encounter for observation for suspected inserted (injected) foreign body ruled out

In addition, as discussed in section II.D.13. of the preamble of this proposed rule, Table 6C.—Invalid Diagnosis Codes, lists the diagnosis codes that are no longer effective October 1, 2020. Included in this table are the following ICD–10–CM diagnosis codes that are currently listed on the Unacceptable Principal Diagnosis edit code list. We are proposing to delete these codes from the Unacceptable Principal Diagnosis edit code list.

ICD-10-CM Code	Code Description
T40.4X5A	Adverse effect of other synthetic narcotics, initial encounter
T40.4X5D	Adverse effect of other synthetic narcotics, subsequent encounter
T40.4X5S	Adverse effect of other synthetic narcotics, sequela
T40.4X6A	Underdosing of other synthetic narcotics, initial encounter
T40.4X6D	Underdosing of other synthetic narcotics, subsequent encounter
T40.4X6S	Underdosing of other synthetic narcotics, sequela

e. Future Enhancement

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38053 through 38054) we noted the importance of ensuring accuracy of the coded data from the reporting, collection, processing, coverage, payment and analysis aspects. Subsequently, in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20235) we stated that we engaged a contractor to assist in the review of the limited coverage and non-covered procedure edits in the MCE that may also be present in other claims processing

systems that are utilized by our MACs. The MACs must adhere to criteria specified within the National Coverage Determinations (NCDs) and may implement their own edits in addition to what is already incorporated into the MCE, resulting in duplicate edits. The objective of this review is to identify where duplicate edits may exist and to determine what the impact might be if these edits were to be removed from the MCE. The contractor is continuing to conduct this review.

We have also noted that the purpose of the MCE is to ensure that errors and inconsistencies in the coded data are recognized during Medicare claims processing. As we indicated in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41228), we are considering whether the inclusion of coverage edits in the MCE necessarily aligns with that specific goal because the focus of coverage edits is on whether or not a particular service is covered for payment purposes and not whether it was coded correctly.

As we continue to evaluate the purpose and function of the MCE with respect to ICD–10, we encourage public input for future discussion. As we have discussed in prior rulemaking, we recognize a need to further examine the current list of edits and the definitions of those edits. We continue to encourage public comments on whether there are additional concerns with the current edits, including specific edits or language that should be removed or revised, edits that should be combined, or new edits that should be added to assist in detecting errors or inaccuracies in the coded data. Comments should be directed to the MS–DRG Classification Change Mailbox located at *MSDRGClassificationChange@cms.hhs.gov* by October 20, 2020.

15. Proposed Changes to Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different MS–DRG within the MDC to which the principal diagnosis is assigned. Therefore, it is necessary to have a decision rule within the GROUPER by which these cases are assigned to a single MS–DRG. The surgical hierarchy, an ordering of surgical classes from most resource-intensive to least resource-intensive, performs that function. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the MS–DRG associated with the most resource-intensive surgical class.

A surgical class can be composed of one or more MS–DRGs. For example, in MDC 11, the surgical class ''kidney transplant'' consists of a single MS–DRG (MS–DRG 652) and the class ''major bladder procedures'' consists of three MS–DRGs (MS–DRGs 653, 654, and 655). Consequently, in many cases, the surgical hierarchy has an impact on more than one MS–DRG. The methodology for determining the most resource-intensive surgical class involves weighting the average resources for each MS–DRG by frequency to determine the weighted average resources for each surgical class. For example, assume surgical class A includes MS–DRGs 001 and 002 and surgical class B includes MS–DRGs 003, 004, and 005. Assume also that the average costs of MS–DRG 001 are higher than that of MS–DRG 003, but the average costs of MS–DRGs 004 and 005 are higher than the average costs of MS–DRG 002. To determine whether surgical class A should be higher or lower than surgical class B in the surgical hierarchy, we would weigh the average costs of each MS–DRG in the class by frequency (that is, by the number of cases in the MS–DRG) to determine average resource consumption for the surgical class. The surgical classes would then be ordered from the class with the highest average resource utilization to that with the lowest, with the exception of ''other O.R. procedures'' as discussed in this proposed rule.

This methodology may occasionally result in assignment of a case involving multiple procedures to the lower-weighted MS–DRG (in the highest, most resource-intensive surgical class) of the available alternatives. However, given that the logic underlying the surgical hierarchy provides that the GROUPER search for the procedure in the most resource-intensive surgical class, in cases involving multiple procedures, this result is sometimes unavoidable.

We note that, notwithstanding the foregoing discussion, there are a few instances when a surgical class with a lower average cost is ordered above a surgical class with a higher average cost. For example, the ''other O.R. procedures'' surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the average costs for the MS–DRG or MS–DRGs in that surgical class may be higher than those for other surgical classes in the MDC. The ''other O.R. procedures'' class is a group of procedures that are only infrequently related to the diagnoses in the MDC, but are still occasionally performed on patients with cases assigned to the MDC with these diagnoses. Therefore, assignment to these surgical classes should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate.

A second example occurs when the difference between the average costs for two surgical classes is very small. We have found that small differences generally do not warrant reordering of the hierarchy because, as a result of reassigning cases on the basis of the hierarchy change, the average costs are likely to shift such that the higher-ordered surgical class has lower average costs than the class ordered below it.

Based on the changes that we are proposing to make in this FY 2021 IPPS/LTCH PPS proposed rule, as discussed in section II.D.2.b. of the preamble of this proposed rule, we are proposing to revise the surgical hierarchy for the Pre-MDC MS–DRGs as follows: In the Pre-MDC MS–DRGs we are proposing to sequence proposed new Pre-MDC MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy) above Pre-MDC MS–DRGs 001 and 002 (Heart Transplant or Implant of Heart Assist System with and without MCC, respectively). We also note that, as discussed in section II.D.2.b. of the preamble of this proposed rule, we are proposing to revise the title for Pre-MDC MS–DRG 016 to ''Autologous Bone Marrow Transplant with CC/MCC''. In addition, based on the changes that we are proposing to make as discussed in section II.D.8.a. of the preamble of this proposed rule, we are also proposing to sequence proposed new Pre-MDC MS–DRG 019 (Simultaneous Pancreas/Kidney Transplant with Hemodialysis) above Pre-MDC MS–DRG 008 (Simultaneous Pancreas/Kidney Transplant) and below Pre-MDC MS–DRG 007 (Lung Transplant).

As discussed in section II.D.4. of the preamble of this proposed rule, we are proposing to delete MS–DRGs 129 and 130 (Major Head and Neck Procedures with CC/MCC or Major Device and without CC/MCC, respectively), MS–DRGs 131 and 132 (Cranial and Facial Procedures with CC/MCC and without CC/MCC, respectively), and MS–DRGs 133 and 134 (Other Ear, Nose, Mouth and Throat O.R. Procedures with CC/MC and without CC/MCC, respectively). Based on the changes we are proposing to make for those MS–DRGs in MDC 03, we are proposing to revise the surgical hierarchy for MDC 03 (Diseases and Disorders of the Ear, Nose, Mouth and Throat) as follows: In MDC 03, we are proposing to sequence proposed new MS–DRGs 140, 141, and 142 (Major Head and Neck Procedures with MCC, with CC, and without CC/MCC, respectively) above proposed new MS–DRGs 143, 144, and 145 (Other Ear,

Nose, Mouth and Throat O.R. Procedures with MCC, with CC, and without CC/MCC, respectively). We are also proposing to sequence proposed new MS–DRGs 143, 144, and 145 above MS–DRGs 135 and 136 (Sinus and Mastoid Procedures with CC/MCC and without CC/MCC, respectively). We also note that, based on the changes that we are proposing to make, as discussed in section II.D.7b of the preamble of this proposed rule, we are proposing to revise the surgical hierarchy for MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) as follows: In MDC 08, we are proposing to sequence proposed new MS–DRGs 521 and 522 (Hip Replacement with Principal Diagnosis of Hip Fracture with and without MCC, respectively) above MS–DRGs 469 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement) and 470 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC). We further note that, based on the changes we are proposing to make, as discussed in section II.D. 8 of the preamble of this proposed rule, we are proposing to revise the surgical hierarchy for MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract) as follows: In MDC 11, we are proposing to sequence proposed new MS–DRGs 650 and 651 (Kidney Transplant with Hemodialysis with and without MCC, respectively) above MS–DRG 652 (Kidney Transplant).

Our proposal for Appendix D MS–DRG Surgical Hierarchy by MDC and MS–DRG of the ICD–10 MS–DRG Definitions Manual Version 38 is illustrated in the following tables.

Proposed Surgical Hierarchy: Pre-MDC MS-DRGs	
Proposed New MS-DRG 018	Chimeric Antigen Receptor (CAR) T-cell Immunotherapy
MS-DRGs 001-002	Heart Transplant or Implant of Heart Assist System
MS-DRGs 003-004	ECMO or Tracheostomy with MV >96 Hours or PDX Except Face, Mouth and Neck
MS-DRGs 005-006	Liver or Intestinal Transplant
MS-DRG 014	Allogeneic Bone Marrow Transplant
MS-DRG 007	Lung Transplant
Proposed New MS-DRG 019	Simultaneous Pancreas/Kidney Transplant with Hemodialysis
MS-DRG 008	Simultaneous Pancreas/Kidney Transplant
MS-DRGs 016-017	Autologous Bone Marrow Transplant
MS-DRG 010	Pancreas
MS-DRG 011-013	Tracheostomy for Face, Mouth and Neck Diagnoses or Laryngectomy

Proposed Surgical Hierarchy: MDC 03	
Proposed New MS-DRGs 140-142	Major Head and Neck Procedures
Proposed New MS-DRGs 143-145	Other Ear, Nose, Mouth and Throat O.R. Procedures
MS-DRGs 135-136	Sinus and Mastoid Procedures

Proposed Surgical Hierarchy: MDC 08	
MS-DRGs 453-455	Combined Anterior/Posterior Spinal Fusion
MS-DRGs 456-458	Spinal Fusion Except Cervical with Spinal Curvature / Malignancy / Infection or Extensive Fusions
MS-DRGs 459-460	Spinal Fusion Except Cervical
MS-DRGs 461-462	Bilateral or Multiple Major Joint Procedures of Lower Extremity
MS-DRGs 463-465	Wound Debridement and Skin Graft Except Hand, for Musculoskeletal and Connective Tissue Disorders
MS-DRGs 466-468	Revision of Hip or Knee Replacement
Proposed New MS-DRGs 521-522	Hip Replacement with Principal Diagnosis of Hip Fracture
MS-DRGs 469-470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity

Proposed Surgical Hierarchy: MDC 11	
Proposed New MS-DRGs 650-651	Kidney Transplant with Hemodialysis
MS-DRG 652	Kidney Transplant

16. Maintenance of the ICD–10–CM and ICD–10–PCS Coding Systems

In September 1985, the ICD–9–CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co-chaired by the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) and CMS, charged with maintaining and updating the ICD–9–CM system. The final update to ICD–9–CM codes was made on October 1, 2013. Thereafter, the name of the Committee was changed to the ICD–10 Coordination and Maintenance Committee, effective with the March 19–20, 2014 meeting. The ICD–10 Coordination and Maintenance Committee addresses updates to the ICD–10–CM and ICD–10–PCS coding systems. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the coding systems to reflect newly developed procedures and technologies and newly identified diseases. The Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The official list of ICD–9–CM diagnosis and procedure codes by fiscal year can be found on the CMS website at: *http://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/codes.html*. The official list of ICD–10–CM and ICD–10–PCS codes can be found on the CMS website at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html*.

The NCHS has lead responsibility for the ICD–10–CM and ICD–9–CM diagnosis codes included in the Tabular List and Alphabetic Index for Diseases, while CMS has lead responsibility for the ICD–10–PCS and ICD–9–CM procedure codes included in the Tabular List and Alphabetic Index for Procedures.

The Committee encourages participation in the previously mentioned process by health-related organizations. In this regard, the Committee holds public meetings for discussion of educational issues and proposed coding changes. These meetings provide an opportunity for representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA), the American Hospital Association (AHA), and various physician specialty groups, as well as individual physicians, health information management professionals, and other members of the public, to contribute ideas on coding matters. After considering the opinions expressed at the public meetings and in writing, the Committee formulates recommendations, which then must be approved by the agencies.

The Committee presented proposals for coding changes for implementation in FY 2021 at a public meeting held on September 10–11, 2019, and finalized the coding changes after consideration of comments received at the meetings and in writing by November 8, 2019.

The Committee held its 2020 meeting on March 17–18, 2020. The deadline for submitting comments on these code proposals was April 17, 2020. It was announced at this meeting that any new diagnosis and procedure codes for which there was consensus of public support and for which complete tabular and indexing changes would be made by June 2020 would be included in the October 1, 2020 update to the ICD–10–CM diagnosis and ICD–10–PCS procedure code sets. As discussed in earlier sections of the preamble of this proposed rule, there are new, revised, and deleted ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes that are captured in Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, and Table 6E.—Revised Diagnosis Code Titles for this proposed rule, which are available via the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. The code titles are adopted as part of the ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee process. Therefore, although we make the code titles available for the IPPS proposed rule, they are not subject to comment in the proposed rule. Because of the length of these tables, they are not published in the Addendum to the proposed rule. Rather, they are available via the internet as discussed in section VI. of the Addendum to the proposed rule.

Live Webcast recordings of the discussions of the diagnosis and procedure codes at the Committee's September 10–11, 2019 meeting and a recording of the virtual meeting held on March 17–18, 2020 can be obtained from the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials*. The materials for the discussions relating to diagnosis codes at the September 10–11, 2019 meeting and March 17–18, 2020 meeting can be found at: *http://www.cdc.gov/nchs/icd/icd10cm_maintenance.html*. These websites also provide detailed information about the Committee, including information on requesting a new code, attending or participating in a Committee meeting, and timeline requirements and meeting dates.

We encourage commenters to address suggestions on coding issues involving diagnosis codes via Email to: *nchsicd10cm@cdc.gov*.

Questions and comments concerning the procedure codes should be submitted via Email to: *ICDProcedureCodeRequest@cms.hhs.gov*.

In the September 7, 2001 final rule implementing the IPPS new technology add-on payments (66 FR 46906), we indicated we would attempt to include proposals for procedure codes that would describe new technology discussed and approved at the Spring meeting as part of the code revisions effective the following October.

Section 503(a) of Public Law 108–173 included a requirement for updating diagnosis and procedure codes twice a year instead of a single update on October 1 of each year. This requirement was included as part of the amendments to the Act relating to recognition of new technology under the IPPS. Section 503(a) of Public Law 108–173 amended section 1886(d)(5)(K) of the Act by adding a clause (vii) which states that the Secretary shall provide for the addition of new diagnosis and procedure codes on April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) until the fiscal year that begins after such date. This requirement improves the recognition of new technologies under the IPPS by providing information on these new technologies at an earlier date. Data will be available 6 months earlier than would be possible with updates occurring only once a year on October 1.

While section 1886(d)(5)(K)(vii) of the Act states that the addition of new diagnosis and procedure codes on April 1 of each year shall not require the Secretary to adjust the payment, or DRG classification, under section 1886(d) of the Act until the fiscal year that begins after such date, we have to update the DRG software and other systems in order to recognize and accept the new codes. We also publicize the code changes and the need for a mid-year systems update by providers to identify the new codes. Hospitals also have to obtain the new code books and encoder updates, and make other system changes

in order to identify and report the new codes.

The ICD–10 (previously the ICD–9–CM) Coordination and Maintenance Committee holds its meetings in the spring and fall in order to update the codes and the applicable payment and reporting systems by October 1 of each year. Items are placed on the agenda for the Committee meeting if the request is received at least 3 months prior to the meeting. This requirement allows time for staff to review and research the coding issues and prepare material for discussion at the meeting. It also allows time for the topic to be publicized in meeting announcements in the **Federal Register** as well as on the CMS website. A complete addendum describing details of all diagnosis and procedure coding changes, both tabular and index, is published on the CMS and NCHS websites in June of each year. Publishers of coding books and software use this information to modify their products that are used by health care providers. This 5-month time period has proved to be necessary for hospitals and other providers to update their systems.

A discussion of this timeline and the need for changes are included in the December 4–5, 2005 ICD–9–CM Coordination and Maintenance Committee Meeting minutes. The public agreed that there was a need to hold the fall meetings earlier, in September or October, in order to meet the new implementation dates. The public provided comment that additional time would be needed to update hospital systems and obtain new code books and coding software. There was considerable concern expressed about the impact this April update would have on providers.

In the FY 2005 IPPS final rule, we implemented section 1886(d)(5)(K)(vii) of the Act, as added by section 503(a) of Public Law 108–173, by developing a mechanism for approving, in time for the April update, diagnosis and procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We also established the following process for making these determinations. Topics considered during the Fall ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting are considered for an April 1 update if a strong and convincing case is made by the requestor at the Committee's public meeting. The request must identify the reason why a new code is needed in April for purposes of the new technology process. The participants at the meeting and those reviewing the Committee meeting materials and live webcast are provided the opportunity to comment on this expedited request. All other topics are considered for the October 1 update. Participants at the Committee meeting are encouraged to comment on all such requests.

There were not any requests submitted for an expedited April 1, 2020 implementation of a new code at the September 10–11, 2019 Committee meeting. However, as announced by the CDC on December 9, 2019, a new ICD–10 emergency code was established by the World Health Organization (WHO) in response to recent occurrences of vaping related disorders. Consistent with this update, the CDC/NCHS implemented a new ICD–10–CM diagnosis code, U07.0 (Vaping-related disorder) for U.S. reporting of vaping-related disorders effective April 1, 2020. In addition, as announced by the CDC, a new emergency code was established by the WHO on January 31, 2020, in response to the 2019 Novel Coronavirus (2019-nCoV) disease outbreak that was declared a public health emergency of international concern. Consistent with this update, the CDC/NCHS implemented a new ICD–10–CM diagnosis code, U07.1 (COVID–19) for U.S. reporting of the 2019 Novel Coronavirus disease effective April 1, 2020. We refer the reader to the CDC web page at *https://www.cdc.gov/nchs/icd/icd10cm.htm* for additional details regarding the implementation of these new diagnosis codes.

We have provided the MS–DRG assignments for these codes effective with discharges on and after April 1, 2020, consistent with our established process for assigning new diagnosis codes. Specifically, we review the predecessor diagnosis code and MS–DRG assignment most closely associated with the new diagnosis code, and consider other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, and the resources utilized for the specific condition/diagnosis. We note that this process does not automatically result in the new diagnosis code being assigned to the same MS–DRG as the predecessor code. Effective with discharges on and after April 1, 2020, diagnosis code U07.0 is assigned to MDC 04 (Diseases and Disorders of the Respiratory System) in MS–DRGs 205 and 206 (Other Respiratory System Diagnoses with and without MCC, respectively), consistent with the assignment of the predecessor diagnosis code. Effective with discharges on and after April 1, 2020, diagnosis code U07.1 is assigned to MDC 04 in MS–DRGs 177, 178 and 179 (Respiratory Infections and Inflammations with MCC, with CC, and without CC/MCC, respectively), MDC 15 (Newborns and Other Neonates with Conditions Originating in Perinatal Period) in MS–DRG 791 (Prematurity with Major Problems) and MS–DRG 793 (Full Term Neonate with Major Problems), and MDC 25 (Human Immunodeficiency Virus Infections) in MS–DRGs 974, 975, and 976 (HIV with Major Related Condition with MCC, with CC, and without CC/MCC, respectively).

These assignments for diagnosis codes U07.0 and U07.1 are reflected in Table 6A—New Diagnosis Codes (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*. As with the other new diagnosis codes and MS–DRG assignments included in Table 6A of this proposed rule, we are soliciting public comments on the most appropriate MDC, MS–DRG, and severity level assignments for these codes for FY 2021, as well as any other options for the GROUPER logic. We also note that Change Request (CR) 11623, Transmittal 4499, titled ''Update to the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD–10–CM) for Vaping Related Disorder'', was issued on January 24, 2020 (available via the internet on the CMS website at: *https://www.cms.gov/files/document/r4499cp.pdf*) regarding the release of an updated version of the ICD–10 MS–DRG Grouper and Medicare Code Editor (MCE) software, Version 37.1, to be effective with discharges on or after April 1, 2020 reflecting new diagnosis code U07.0. The updated software, along with the updated ICD–10 MS–DRG V37.1 Definitions Manual and the Definitions of Medicare Code Edits V37.1 manual was made available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPSMS–DRG-Classifications-and-Software*. In response to the implementation of diagnosis code U07.1 (COVID–19), we subsequently released a new updated version of the ICD–10 MS–DRG Grouper and Medicare Code Editor (MCE) software, Version 37.1 R1, effective with discharges on or after April 1, 2020 reflecting this new code, which replaced the ICD–10 MS–DRG Grouper and Medicare Code Editor (MCE) software, Version 37.1. The updated software, along with the updated ICD–10 MS–DRG V37.1 R1 Definitions Manual and the Definitions of Medicare Code Edits V37.1 R1 manual are available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/*

AcuteInpatientPPS/MS-DRG-Classifications-and-Software.

ICD–9–CM addendum and code title information is published on the CMS website at: *http://www.cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/index.html?redirect=/icd9ProviderDiagnosticCodes/01overview.asp#TopofPage.* ICD–10–CM and ICD–10–PCS addendum and code title information is published on the CMS website at: *http://www.cms.gov/Medicare/Coding/ICD10/index.html.* CMS also sends copies of all ICD–10–CM and ICD–10–PCS coding changes to its Medicare contractors for use in updating their systems and providing education to providers.

Information on ICD–10–CM diagnosis codes, along with the Official ICD–10–CM Coding Guidelines, can also be found on the CDC website at: *http://www.cdc.gov/nchs/icd/icd10.htm.* Additionally, information on new, revised, and deleted ICD–10–CM diagnosis and ICD–10–PCS procedure codes is provided to the AHA for publication in the *Coding Clinic for ICD–10.* AHA also distributes coding update information to publishers and software vendors.

The following chart shows the number of ICD–10–CM and ICD–10–PCS codes and code changes since FY 2016 when ICD–10 was implemented.

Total Number of Codes and Changes in Total Number of Codes per Fiscal Year ICD-10-CM and ICD-10-PCS Codes

Fiscal Year	Number	Change
FY 2016		
ICD-10-CM	69,823	
ICD-10-PCS	71,974	
FY 2017		
ICD-10-CM	71,486	+1,663
ICD-10-PCS	75,789	+3,815
FY 2018		
ICD-10-CM	71,704	+218
ICD-10-PCS	78,705	+2,916
FY 2019		
ICD-10-CM	71,932	+228
ICD-10-PCS	78,881	+176
FY 2020		
ICD-10-CM	72,184	+252
ICD-10-PCS	77,559	-1,322
FY 2021 (Proposed)		
ICD-10-CM	72,616	+432
ICD-10-PCS	77,781	+222

As mentioned previously, the public is provided the opportunity to comment on any requests for new diagnosis or procedure codes discussed at the ICD–10 Coordination and Maintenance Committee meeting.

17. Replaced Devices Offered Without Cost or With a Credit

a. Background

In the FY 2008 IPPS final rule with comment period (72 FR 47246 through 47251), we discussed the topic of Medicare payment for devices that are replaced without cost or where credit for a replaced device is furnished to the hospital. We implemented a policy to reduce a hospital's IPPS payment for certain MS–DRGs where the implantation of a device that subsequently failed or was recalled determined the base MS–DRG assignment. At that time, we specified that we will reduce a hospital's IPPS payment for those MS–DRGs where the hospital received a credit for a replaced device equal to 50 percent or more of the cost of the device.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51556 through 51557), we clarified this policy to state that the policy applies if the hospital received a credit equal to 50 percent or more of the cost of the replacement device and issued instructions to hospitals accordingly.

b. Proposed Changes for FY 2021

As discussed in section II.D.4. of the preamble of this proposed rule, for FY 2021, under MDC 03, we are proposing to delete MS–DRGs 129 and 130 and to

add new MS–DRGs 140, 141, and 142 (Major Head and Neck Procedures with MCC, with CC, and without CC/MCC, respectively). A subset of the procedures currently assigned to MS–DRGs 129 and 130 are being proposed for assignment to proposed new MS–DRGs 140, 141, and 142.

Additionally, as discussed in section II.D.7.b. of the preamble of this proposed rule, for FY 2021, under MDC 08, we are proposing to create new MS–DRGs 551 and 552 (Hip Replacement with Principal Diagnosis of Hip Fracture with and without MCC, respectively). A subset of the procedures currently assigned to MS–DRGs 469 through 470 are being proposed for assignment to proposed new MS–DRGs 551 and 552.

As stated in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24409), we generally map new MS–DRGs onto the list when they are formed from procedures previously assigned to MS–DRGs that are already on the list. Currently, MS–DRGs 129, 130, 469 and 470 are on the list of MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit. Therefore, if the applicable proposed MS–DRG changes are finalized, we also would add proposed new MS–DRGs 140, 141, 142, 551 and 552 to the list of MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit and make conforming changes as reflected in the table. We are also proposing to continue to include the existing MS–DRGs currently subject to the policy as also displayed in the table.

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MDC	MS-DRG	MS-DRG Title
Pre-MDC	001	Heart Transplant or Implant of Heart Assist System with MCC
Pre-MDC	002	Heart Transplant or Implant of Heart Assist System without MCC
01	023	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator
01	024	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC
01	025	Craniotomy and Endovascular Intracranial Procedures with MCC
01	026	Craniotomy and Endovascular Intracranial Procedures with CC
01	027	Craniotomy and Endovascular Intracranial Procedures without CC/MCC
01	040	Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC
01	041	Peripheral, Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulator
01	042	Peripheral, Cranial Nerve and Other Nervous System Procedures without CC/MCC
03	129	Delete
03	130	Delete
03	141	Major Head and Neck Procedures with MCC
03	142	Major Head and Neck Procedures with CC
03	143	Major Head and Neck Procedures without CC/MCC
05	215	Other Heart Assist System Implant
05	216	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with MCC
05	217	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with CC
05	218	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization without CC/MCC
05	219	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with MCC
05	220	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with CC
05	221	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization without CC/MCC
05	222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/Heart Failure/Shock with MCC
05	223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/Heart Failure/Shock without MCC
05	224	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/Heart Failure/Shock with MCC
05	225	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/Heart Failure/Shock without MCC

MDC	MS-DRG	MS-DRG Title
05	226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC
05	227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC
05	242	Permanent Cardiac Pacemaker Implant with MCC
05	243	Permanent Cardiac Pacemaker Implant with CC
05	244	Permanent Cardiac Pacemaker Implant without CC/MCC
05	245	AICD Generator Procedures
05	258	Cardiac Pacemaker Device Replacement with MCC
05	259	Cardiac Pacemaker Device Replacement without MCC
05	260	Cardiac Pacemaker Revision Except Device Replacement with MCC
05	261	Cardiac Pacemaker Revision Except Device Replacement with CC
05	262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC
05	265	AICD Lead Procedures
05	266	Endovascular Cardiac Valve Replacement And Supplement Procedures with MCC
05	267	Endovascular Cardiac Valve Replacement And Supplement Procedures without MCC
05	268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC
05	269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC
05	270	Other Major Cardiovascular Procedures with MCC
05	271	Other Major Cardiovascular Procedures with CC
05	272	Other Major Cardiovascular Procedures without CC/MCC
05	319	Other Endovascular Cardiac Valve Procedures with MCC
05	320	Other Endovascular Cardiac Valve Procedures without MCC
08	461	Bilateral or Multiple Major Joint Procedures Of Lower Extremity with MCC
08	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC
08	466	Revision of Hip or Knee Replacement with MCC
08	467	Revision of Hip or Knee Replacement with CC
08	468	Revision of Hip or Knee Replacement without CC/MCC
08	469	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement
08	470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC
08	551	Hip Replacement with Principal Diagnosis of Hip Fracture with MCC
08	552	Hip Replacement with Principal Diagnosis of Hip Fracture without MCC

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The final list of MS–DRGs subject to the IPPS policy for replaced devices offered without cost or with a credit will be included in the FY2021 IPPS/LTCH

PPS final rule and also will be issued to providers in the form of a Change Request (CR).

E. Recalibration of the FY 2021 MS–DRG Relative Weights

Beginning in FY 2007, we implemented relative weights for DRGs based on cost report data instead of charge information. We refer readers to the FY 2007 IPPS final rule (71 FR 47882) for a detailed discussion of our final policy for calculating the cost based DRG relative weights and to the FY 2008 IPPS final rule with comment period (72 FR 47199) for information on how we blended relative weights based on the CMS DRGs and MS DRGs. We also refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56785 through 56787) for a detailed discussion of the history of changes to the number of cost centers used in calculating the DRG relative weights. Since FY 2014, we have calculated the IPPS MS DRG relative weights using 19 CCRs, which now include distinct CCRs for implantable devices, MRIs, CT scans, and cardiac catheterization.

1. Data Sources for Developing the Relative Weights

Consistent with our established policy, in developing the MS–DRG relative weights for FY 2021, we are proposing to use two data sources: claims data and cost report data. The claims data source is the MedPAR file, which includes fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. The FY 2019 MedPAR data used in this proposed rule include discharges occurring on October 1, 2018, through September 30, 2019, based on bills received by CMS through December 31, 2019, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS). The FY 2019 MedPAR file used in calculating the proposed relative weights includes data for approximately 9,184,114 Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from this analysis. These discharges are excluded when the MedPAR ''GHO Paid'' indicator field on the claim record is equal to ''1'' or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR ''Indirect Medical Education (IME)'' payment field, indicating that the claim was an ''IME only'' claim submitted by a teaching hospital on behalf of a beneficiary enrolled in a Medicare Advantage managed care plan. In addition, the December 31, 2019 update of the FY 2019 MedPAR file complies with version 5010 of the X12 HIPAA Transaction and Code Set Standards, and includes a variable called ''claim type.'' Claim type ''60'' indicates that the claim was an inpatient claim paid as fee-for-service. Claim types ''61,'' ''62,'' ''63,'' and ''64'' relate to encounter claims, Medicare Advantage IME claims, and HMO no-pay claims. Therefore, the calculation of the proposed relative weights for FY 2021 also excludes claims with claim type values not equal to ''60.'' The data exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken. We note that the proposed FY 2021 relative weights are based on the ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes from the FY 2019 MedPAR claims data, grouped through the ICD–10 version of the proposed FY 2021 GROUPER (Version 38).

The second data source used in the cost-based relative weighting methodology is the Medicare cost report data files from the HCRIS. Normally, we use the HCRIS dataset that is 3 years prior to the IPPS fiscal year. Specifically, we used cost report data from the December 31, 2019 update of the FY 2018 HCRIS for calculating the proposed FY 2021 cost-based relative weights. Consistent with our historical practice, for this FY 2021 proposed rule, we are providing the version of the HCRIS from which we calculated these proposed 19 CCRs 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 2021 IPPS Proposed Rule Home Page'' or ''Acute Inpatient Files for Download.''

2. Methodology for Calculation of the Relative Weights

a. General

We calculated the proposed FY 2021 relative weights based on 19 CCRs, as we did for FY 2020. The methodology we are proposing to use to calculate the FY 2021 MS–DRG cost-based relative weights based on claims data in the FY 2019 MedPAR file and data from the FY 2018 Medicare cost reports is as follows:

- To the extent possible, all the claims were regrouped using the proposed FY 2021 MS–DRG classifications discussed in sections II.B. and II.F. of the preamble of this proposed rule.
- The transplant cases that were used to establish the proposed relative weights for heart and heart-lung, liver and/or intestinal, and lung transplants (MS–DRGs 001, 002, 005, 006, and 007, respectively) were limited to those Medicare-approved transplant centers that have cases in the FY 2019 MedPAR file. (Medicare coverage for heart, heart-lung, liver and/or intestinal, and lung transplants is limited to those facilities that have received approval from CMS as transplant centers.)
- Organ acquisition costs for kidney, heart, heart-lung, liver, lung, pancreas, and intestinal (or multivisceral organs) transplants continue to be paid on a reasonable cost basis. Because these acquisition costs are paid separately from the prospective payment rate, it is necessary to subtract the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.
- Claims with total charges or total lengths of stay less than or equal to zero were deleted. Claims that had an amount in the total charge field that differed by more than $30.00 from the sum of the routine day charges, intensive care charges, pharmacy charges, implantable devices charges, supplies and equipment charges, therapy services charges, operating room charges, cardiology charges, laboratory charges, radiology charges, other service charges, labor and delivery charges, inhalation therapy charges, emergency room charges, blood and blood products charges, anesthesia charges, cardiac catheterization charges, CT scan charges, and MRI charges were also deleted.
- At least 92.8 percent of the providers in the MedPAR file had charges for 14 of the 19 cost centers. All claims of providers that did not have charges greater than zero for at least 14 of the 19 cost centers were deleted. In other words, a provider must have no more than five blank cost centers. If a provider did not have charges greater than zero in more than five cost centers, the claims for the provider were deleted.
- Statistical outliers were eliminated by removing all cases that were beyond 3.0 standard deviations from the geometric mean of the log distribution of both the total charges per case and the total charges per day for each MS–DRG.
- Effective October 1, 2008, because hospital inpatient claims include a POA indicator field for each diagnosis present on the claim, only for purposes of relative weight-setting, the POA indicator field was reset to ''Y'' for ''Yes'' for all claims that otherwise have an ''N'' (No) or a ''U'' (documentation insufficient to determine if the

condition was present at the time of inpatient admission) in the POA field.

Under current payment policy, the presence of specific HAC codes, as indicated by the POA field values, can generate a lower payment for the claim. Specifically, if the particular condition is present on admission (that is, a ''Y'' indicator is associated with the diagnosis on the claim), it is not a HAC, and the hospital is paid for the higher severity (and, therefore, the higher weighted MS–DRG). If the particular condition is not present on admission (that is, an ''N'' indicator is associated with the diagnosis on the claim) and there are no other complicating conditions, the DRG GROUPER assigns the claim to a lower severity (and, therefore, the lower weighted MS–DRG) as a penalty for allowing a Medicare inpatient to contract a HAC. While the POA reporting meets policy goals of encouraging quality care and generates program savings, it presents an issue for the relative weight-setting process. Because cases identified as HACs are likely to be more complex than similar cases that are not identified as HACs, the charges associated with HAC cases are likely to be higher as well. Therefore, if the higher charges of these HAC claims are grouped into lower severity MS–DRGs prior to the relative weight-setting process, the relative weights of these particular MS–DRGs would become artificially inflated, potentially skewing the relative weights. In addition, we want to protect the integrity of the budget neutrality process by ensuring that, in estimating payments, no increase to the standardized amount occurs as a result of lower overall payments in a previous year that stem from using weights and case-mix that are based on lower severity MS–DRG assignments. If this would occur, the anticipated cost savings from the HAC policy would be lost.

To avoid these problems, we reset the POA indicator field to ''Y'' only for relative weight-setting purposes for all claims that otherwise have an ''N'' or a ''U'' in the POA field. This resetting ''forced'' the more costly HAC claims into the higher severity MS–DRGs as appropriate, and the relative weights calculated for each MS–DRG more closely reflect the true costs of those cases.

In addition, in the FY 2013 IPPS/LTCH PPS final rule, for FY 2013 and subsequent fiscal years, we finalized a policy to treat hospitals that participate in the Bundled Payments for Care Improvement (BPCI) initiative the same as prior fiscal years for the IPPS payment modeling and ratesetting process without regard to hospitals' participation within these bundled payment models (77 FR 53341 through 53343). Specifically, because acute care hospitals participating in the BPCI Initiative still receive IPPS payments under section 1886(d) of the Act, we include all applicable data from these subsection (d) hospitals in our IPPS payment modeling and ratesetting calculations as if the hospitals were not participating in those models under the BPCI initiative. We refer readers to the FY 2013 IPPS/LTCH PPS final rule for a complete discussion on our final policy for the treatment of hospitals participating in the BPCI initiative in our ratesetting process. For additional information on the BPCI initiative, we refer readers to the CMS' Center for Medicare and Medicaid Innovation's website at: *http://innovation.cms.gov/initiatives/Bundled-Payments/index.html* and to section IV.H.4. of the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53341 through 53343).

The participation of hospitals in the BPCI initiative concluded on September 30, 2018. The participation of hospitals in the BPCI Advanced model started on October 1, 2018. The BPCI Advanced model, tested under the authority of section 1115A of the Act, is comprised of a single payment and risk track, which bundles payments for multiple services beneficiaries receive during a Clinical Episode. Acute care hospitals may participate in BPCI Advanced in one of two capacities: As a model Participant or as a downstream Episode Initiator. Regardless of the capacity in which they participate in the BPCI Advanced model, participating acute care hospitals will continue to receive IPPS payments under section 1886(d) of the Act. Acute care hospitals that are Participants also assume financial and quality performance accountability for Clinical Episodes in the form of a reconciliation payment. For additional information on the BPCI Advanced model, we refer readers to the BPCI Advanced web page on the CMS Center for Medicare and Medicaid Innovation's website at: *https://innovation.cms.gov/initiatives/bpci-advanced/*. Consistent with our policy for FY 2020, and consistent with how we have treated hospitals that participated in the BPCI Initiative, for FY 2021, we continue to believe it is appropriate to include all applicable data from the subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations because, as noted previously, these hospitals are still receiving IPPS payments under section 1886(d) of the Act. Consistent with FY 2020 IPPS/LTCH PPS final rule, we also are proposing to include all applicable data from subsection (d) hospitals participating in the Comprehensive Care for Joint Replacement (CJR) Model in our IPPS payment modeling and ratesetting calculations.

The charges for each of the 19 cost groups for each claim were standardized to remove the effects of differences in area wage levels, IME and DSH payments, and for hospitals located in Alaska and Hawaii, the applicable cost-of-living adjustment. Because hospital charges include charges for both operating and capital costs, we standardized total charges to remove the effects of differences in geographic adjustment factors, cost-of-living adjustments, and DSH payments under the capital IPPS as well. Charges were then summed by MS–DRG for each of the 19 cost groups so that each MS–DRG had 19 standardized charge totals. Statistical outliers were then removed. These charges were then adjusted to cost by applying the proposed national average CCRs developed from the FY 2018 cost report data.

The 19 cost centers that we used in the proposed relative weight calculation are shown in a supplemental data file posted via the internet on the CMS website for this proposed rule and available at *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. The supplemental data file shows the lines on the cost report and the corresponding revenue codes that we used to create the proposed 19 national cost center CCRs. If we receive comments about the groupings, we may consider those comments as we finalize our policy.

We are inviting public comments on our proposals related to recalibration of the proposed FY 2021 relative weights and the changes in relative weights from FY 2020.

We note that in the FY 2020 IPPS/LTCH PPS final rule, we adopted a temporary one-time measure for FY 2020 for an MS–DRG where the FY 2018 relative weight declined by 20 percent from the FY 2017 relative weight, and the FY 2020 relative weight would have declined by 20 percent or more from the FY 2019 relative weight, which was maintained at the FY 2018 relative weight. For an MS–DRG meeting this criterion, the FY 2020 relative weight was set equal to the FY 2019 relative weight, which in turn had been set equal to the FY 2018 relative weight (84 FR 42167). For FY 2020, the only MS–DRG meeting this criterion was MS–

DRG 215. We are inviting public comments on the proposed FY 2021 weight for MS–DRG 215 (Other Heart Assist System Implant) as set forth in Table 5 associated with this proposed rule, including comments on whether we should consider a policy under sections 1886(d)(4)(B) and (C) of the Act similar to the measure adopted in the FY 2020 IPPS/LTCH PPS final rule to maintain the FY 2021 relative weight equal to the FY 2020 relative weight for MS–DRG 215, or an alternative approach such as averaging the FY 2020 relative weight and the otherwise applicable FY 2021 weight.

b. Proposed Relative Weight Calculation for Proposed New MS–DRG 018 for CAR T-Cell Therapy

As discussed in section II.D.2.b. of this proposed rule, we are proposing to create new MS–DRG 018 for cases that include procedures describing CAR T-cell therapies, which are currently reported using ICD–10–PCS procedure codes XW033C3 or XW043C3. As discussed in section IV.I. of this proposed rule, given the high cost of the CAR T-cell product, we are proposing a differential payment for cases where the CAR T-cell product is provided without cost as part of a clinical trial to ensure that the payment amount for CAR T-cell therapy clinical trial cases appropriately reflects the relative resources required for providing CAR T-cell therapy as part of a clinical trial.

We also believe it would be appropriate to modify our existing relative weight methodology to ensure that the relative weight for proposed new MS–DRG 018 appropriately reflects the relative resources required for providing CAR T-cell therapy outside of a clinical trial, while still accounting for the clinical trial cases in the overall average cost for all MS–DRGs. Specifically, we are proposing that clinical trial claims that group to proposed new MS–DRG 018 would not be included when calculating the average cost for proposed new MS–DRG 018 that is used to calculate the relative weight for this MS–DRG, so that the relative weight reflects the costs of the CAR T-cell therapy drug. Consistent with our analysis of the FY 2019 MedPAR claims data as discussed in section IV.I. of this proposed rule, we identified clinical trial claims as claims that contain ICD–10–CM diagnosis code Z00.6 or contain standardized drug charges of less than $373,000, which is the average sales price of KYMRIAH and YESCARTA, which are the two CAR T-cell medicines approved to treat relapsed/refractory diffuse large B-cell lymphoma as of the time of the development of this proposed rule. We are also proposing to calculate the following adjustment to account for the CAR T-cell therapy cases identified as clinical trial cases in calculating the national average standardized cost per case that is used to calculate the relative weights for all MS–DRGs and for purposes of budget neutrality and outlier simulations:

- Calculate the average cost for cases to be assigned to proposed new MS–DRG 018 that contain ICD–10–CM diagnosis code Z00.6 or contain standardized drug charges of less than $373,000.
- Calculate the average cost for cases to be assigned to proposed new MS–DRG 018 that do not contain ICD–10–CM diagnosis code Z00.6 or standardized drug charges of at least $373,000.
- Calculate an adjustor by dividing the average cost calculated in step 1 by the average cost calculated in step 2.
- Apply the adjustor calculated in step 3 to the cases identified in step 1 as clinical trial cases, then add this adjusted case count to the non-clinical trial case count prior to calculating the average cost across all MS–DRGs.

Each year, when we calculate the relative weights, we use a transfer-adjusted case count for each MS–DRG, which accounts for payment adjustments resulting from our postacute care transfer policy. This process is described in the FY 2006 IPPS/LTCH PPS final rule (70 FR 47697). We propose to apply this adjustor to the case count for MS–DRG 018 in a similar manner. We propose to first calculate the transfer-adjusted case count for MS–DRG 018, and then further adjust the transfer-adjusted case count by the adjustor described previously. Then, we propose to use this adjusted case count for MS–DRG 018 in calculating the national average cost per case, which is used in the calculation of the relative weights. Based on the December 2019 update of the FY 2019 MedPAR file, we estimate that the average costs of CAR T-cell therapy cases identified as clinical trial cases ($42,164) are 15 percent of the average costs of CAR T-cell therapy cases identified as non-clinical trial cases ($277,592), and therefore, in calculating the national average cost per case, each case identified as a clinical trial case was adjusted to 0.15. We expect to recalculate this adjustor for the CAR T cell therapy clinical trial cases for the final rule based on the updated data available. We also note that we are applying this proposed adjustor for CAR T-cell therapy clinical trial cases for purposes of budget neutrality and outlier simulations, as discussed further in section II.A. of the Addendum to this proposed rule.

We are inviting public comments on our proposal.

3. Development of Proposed National Average CCRs

We developed the proposed national average CCRs as follows:

Using the FY 2018 cost report data, we removed CAHs, Indian Health Service hospitals, all-inclusive rate hospitals, and cost reports that represented time periods of less than 1 year (365 days). We included hospitals located in Maryland because we include their charges in our claims database. Then we created CCRs for each provider for each cost center (see the supplemental data file for line items used in the calculations) and removed any CCRs that were greater than 10 or less than 0.01. We normalized the departmental CCRs by dividing the CCR for each department by the total CCR for the hospital for the purpose of trimming the data. Then we took the logs of the normalized cost center CCRs and removed any cost center CCRs where the log of the cost center CCR was greater or less than the mean log plus/minus 3 times the standard deviation for the log of that cost center CCR. Once the cost report data were trimmed, we calculated a Medicare-specific CCR. The Medicare-specific CCR was determined by taking the Medicare charges for each line item from Worksheet D–3 and deriving the Medicare-specific costs by applying the hospital-specific departmental CCRs to the Medicare-specific charges for each line item from Worksheet D–3. Once each hospital's Medicare-specific costs were established, we summed the total Medicare-specific costs and divided by the sum of the total Medicare-specific charges to produce national average, charge-weighted CCRs.

After we multiplied the total charges for each MS–DRG in each of the 19 cost centers by the corresponding national average CCR, we summed the 19 ''costs'' across each MS–DRG to produce a total standardized cost for the MS–DRG. The average standardized cost for each MS–DRG was then computed as the total standardized cost for the MS–DRG divided by the transfer-adjusted case count for the MS–DRG. The average cost for each MS–DRG was then divided by the national average standardized cost per case to determine the proposed relative weight.

The proposed FY 2021 cost-based relative weights were then normalized by a proposed adjustment factor of 1.818392 so that the average case weight

after recalibration was equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

The proposed 19 national average CCRs for FY 2021 are as follows:

Group	CCR
Routine Days	0.422
Intensive Days	0.347
Drugs	0.190
Supplies & Equipment	0.304
Implantable Devices	0.300
Inhalation Therapy	0.148
Therapy Services	0.291
Anesthesia	0.074
Labor & Delivery	0.369
Operating Room	0.169
Cardiology	0.095
Cardiac Catheterization	0.102
Laboratory	0.108
Radiology	0.138
MRIs	0.070
CT Scans	0.034
Emergency Room	0.149
Blood and Blood Products	0.272
Other Services	0.350
Routine Days	0.422
Intensive Days	0.347

Since FY 2009, the relative weights have been based on 100 percent cost weights based on our MS–DRG grouping system.

When we recalibrated the DRG weights for previous years, we set a threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. We are proposing to use that same case threshold in recalibrating the proposed MS–DRG relative weights for FY 2021. Using data from the FY 2019 MedPAR file, there were 7 MS–DRGs that contain fewer than 10 cases. For FY 2021, because we do not have sufficient MedPAR data to set accurate and stable cost relative weights for these low-volume MS–DRGs, we are proposing to compute relative weights for the low-volume MS–DRGs by adjusting their final FY 2020 relative weights by the percentage change in the average weight of the cases in other MS–DRGs from FY 2020 to FY 2021. The crosswalk table is as follows.

Low-Volume MS-DRG	MS-DRG Title	Crosswalk to MS-DRG
789	Neonates, Died or Transferred to Another Acute Care Facility	Final FY 2020 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
790	Extreme Immaturity or Respiratory Distress Syndrome, Neonate	Final FY 2020 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
791	Prematurity with Major Problems	Final FY 2020 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
792	Prematurity without Major Problems	Final FY 2020 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
793	Full-Term Neonate with Major Problems	Final FY 2020 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
794	Neonate with Other Significant Problems	Final FY 2020 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
795	Normal Newborn	Final FY 2020 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)

G. Proposed Add-On Payments for New Services and Technologies for FY 2021

1. Background

Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies (sometimes collectively referred to in this section as ''new technologies'') under the IPPS. Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for new technology add-on payment if, based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate. We note that, beginning with discharges occurring in FY 2008, CMS transitioned from CMS–DRGs to MS–DRGs. The regulations at 42 CFR 412.87 implement these provisions and § 412.87(b) specifies three criteria for a new medical service or technology to receive the additional payment: (1) The medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. In addition, certain transformative new devices and Qualified Infectious Disease Products may qualify under an alternative inpatient new technology add-on payment pathway, as set forth in the regulations at § 412.87(c) and (d). In this rule, we highlight some of the major statutory and regulatory provisions relevant to the new technology add-on payment criteria, as well as other information. For a complete discussion on the new technology add-on payment criteria, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51572 through 51574) and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42300).

a. New Technology Add On Payment Criteria

(1) Newness Criterion

Under the first criterion, as reflected in § 412.87(b)(2), a specific medical service or technology will be considered ''new'' for purposes of new medical service or technology add-on payments until such time as Medicare data are available to fully reflect the cost of the technology in the MS–DRG weights through recalibration. We note that we do not consider a service or technology to be new if it is substantially similar to one or more existing technologies. That is, even if a medical product receives a new FDA approval or clearance, it may not necessarily be considered ''new'' for purposes of new technology add-on payments if it is ''substantially similar'' to another medical product that was approved or cleared by FDA and has been on the market for more than 2 to 3 years. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814), we established criteria for evaluating whether a new technology is substantially similar to an existing technology, specifically: (1) Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) whether a product is assigned to the same or a different MS–DRG; and (3) whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If a technology meets all three of these criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments. For a detailed discussion of the criteria for substantial similarity, we refer readers to the FY 2006 IPPS final rule (70 FR 47351 through 47352), and the FY 2010 IPPS/LTCH PPS final rule (74 FR 43813 through 43814).

(2) Cost Criterion

Under the second criterion, § 412.87(b)(3) further provides that, to be eligible for the add-on payment for new medical services or technologies, the MS–DRG prospective payment rate otherwise applicable to discharges involving the new medical service or technology must be assessed for adequacy. Under the cost criterion, consistent with the formula specified in section 1886(d)(5)(K)(ii)(I) of the Act, to assess the adequacy of payment for a new technology paid under the applicable MS–DRG prospective payment rate, we evaluate whether the charges for cases involving the new technology exceed certain threshold amounts. The MS–DRG threshold amounts generally used in evaluating new technology add-on payment applications for FY 2021 are presented in a data file that is available, along with the other data files associated with the FY 2020 IPPS/LTCH PPS final rule and correction notice, on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.* However, as we discuss in section II.F.5.i. of the

preamble of this proposed rule, we are proposing to apply the proposed threshold value for proposed new MS–DRG 018 in evaluating the cost criterion for the CAR T-cell therapy technologies for purposes of FY 2021 new technology add-on payments.

As finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41275), beginning with FY 2020, we include the thresholds applicable to the next fiscal year (previously included in Table 10 of the annual IPPS/LTCH PPS proposed and final rules) in the data files associated with the prior fiscal year. Accordingly, the proposed thresholds for applications for new technology add-on payments for FY 2022 are presented in a data file that is available on the CMS website, along with the other data files associated with this FY 2021 proposed rule, by clicking on the FY 2021 IPPS Proposed Rule Home Page at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*. We note that, under our proposal discussed in section II.F.5.i of the preamble of this proposed rule, beginning with FY 2022, we would use the proposed threshold values associated with the proposed rule for that fiscal year to evaluate the cost criterion for all other applications for new technology add-on payments and previously approved technologies that may continue to receive new technology add-on payments, if those technologies would be assigned to a proposed new MS–DRG for that same fiscal year. In the September 7, 2001 final rule that established the new technology add-on payment regulations (66 FR 46917), we discussed that applicants should submit a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Specifically, applicants should submit a sample of sufficient size to enable us to undertake an initial validation and analysis of the data. We also discussed in the September 7, 2001 final rule (66 FR 46917) the issue of whether the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule at 45 CFR parts 160 and 164 applies to claims information that providers submit with applications for new medical service or technology add-on payments. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51573) for complete information on this issue.

b. Substantial Clinical Improvement Criterion

Under the third criterion at § 412.87(b)(1), a medical service or technology must represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42292) we prospectively codified in our regulations at § 412.87(b) the following aspects of how we evaluate substantial clinical improvement for purposes of new technology add-on payments under the IPPS:

- The totality of the circumstances is considered when making a determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries.
- A determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries means—

++ The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments;

++ The new medical service or technology 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 allowed by currently available methods, and there must also be evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient;

++ The use of the new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available as demonstrated by one or more of the following: A reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; a decreased rate of at least one subsequent diagnostic or therapeutic intervention; a decreased number of future hospitalizations or physician visits; a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; an improvement in one or more activities of daily living; an improved quality of life; or, a demonstrated greater medication adherence or compliance; or

++ The totality of the circumstances otherwise demonstrates that the new medical service or technology substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

- Evidence from the following published or unpublished information sources from within the United States or elsewhere may be sufficient to establish that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries: Clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.
- The medical condition diagnosed or treated by the new medical service or technology may have a low prevalence among Medicare beneficiaries.
- The new medical service or technology may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new medical service or technology.

We refer the reader to the FY 2020 IPPS/LTCH PPS final rule for additional discussion of the evaluation of substantial clinical improvement for purposes of new technology add-on payments under the IPPS.

We note, consistent with the discussion in the FY 2003 IPPS Final Rule (67 FR 50015), although we are affiliated with the FDA and we do not question the FDA's regulatory responsibility for decisions related to marketing authorization (for example, approval, clearance, etc.), we do not use FDA criteria to determine what drugs, devices, or technologies qualify for new technology add-on payments under Medicare. Our criteria do not depend on the standard of safety and efficacy on which the FDA relies but on a demonstration of substantial clinical improvement in the Medicare population (particularly patients over age 65).

c. Alternative Inpatient New Technology Add-On Payment Pathway

Under § 412.87(c) and (d) of the regulations, beginning with applications for new technology add-on payments for FY 2021, certain transformative new devices and Qualified Infectious Disease Products (QIDPs) may qualify for the new technology add-on payment under

an alternative pathway, as described in this section. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule for complete discussion on this policy (84 FR 42292 through 42297). We note, in section II.F.9.b. of this preamble, we are proposing to expand our current alternative new technology add-on payment pathway for QIDPs to include products approved under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) pathway. In addition, we are proposing to refer more broadly to ''certain antimicrobial products'' rather than specifying the particular FDA programs for antimicrobial products (that is, QIDPs and LPADs) that are the subject of the alternative new technology add-on payment pathway. (We refer the reader to section II.F.9.b. of this preamble below for a complete discussion regarding this proposal.) We note that a technology is not required to have the specified FDA designation at the time the new technology add-on payment application is submitted. CMS will review the application based on the information provided by the applicant under the alternative pathway specified by the applicant. However, to receive approval for the new technology add-on payment under that alternative pathway, the technology must have the applicable designation and meet all other requirements in the regulations in § 412.87(c) and (d), as applicable.

(1) Alternative Pathway for Certain Transformative New Devices

For applications received for new technology add-on payments for FY 2021 and subsequent fiscal years, if a medical device is part of FDA's Breakthrough Devices Program nd received FDA marketing authorization, it will be considered new and not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and will not need to meet the requirement under § 412.87(b)(1) that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. This policy is codified at § 412.87(c). Under this alternative pathway, a medical device that has received FDA marketing authorization (that is, has been approved or cleared by, or had a De Novo classification request granted by, FDA) and that is part of FDA's Breakthrough Devices Program will need to meet the cost criterion under § 412.87(b)(3), as reflected in § 412.87(c)(3), and will be considered new as reflected in § 412.87(c)(2). We note, in section II.F.8. of this preamble, we are clarifying our policy that a new medical device under this alternative pathway must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation. (We refer the reader to section II.F.8. of this preamble below for a complete discussion regarding this clarification.)

(2) Alternative Pathway for Qualified Infectious Disease Products (QIDPs)

For applications received for new technology add-on payments for FY 2021 and subsequent fiscal years, if a technology is designated by FDA as a QIDP and received FDA marketing authorization, it will be considered new and not substantially similar to an existing technology for purposes of new technology add-on payments and will not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. We codified this policy at § 412.87(d). Under this alternative pathway for QIDPs, a medical product that has received FDA marketing authorization and is designated by FDA as a QIDP will need to meet the cost criterion under § 412.87(b)(3), as reflected in § 412.87(d)(3), and will be considered new as reflected in § 412.87(d)(2).

We refer the reader to the FY 2020 IPPS/LTCH PPS final rule for complete discussion on this policy (84 FR 42292 through 42297). We note, in section II.F.9.b. of this preamble, we are clarifying a new medical product seeking approval for the new technology add-on payment under the alternative pathway for QIDPs must receive marketing authorization for the indication covered by the QIDP designation. (We refer the reader to section II.F.9.b. of this preamble. below for a complete discussion regarding this clarification.)

d. Additional Payment for New Medical Service or Technology

The new medical service or technology add-on payment policy under the IPPS provides additional payments for cases with relatively high costs involving eligible new medical services or technologies, while preserving some of the incentives inherent under an average-based prospective payment system. The payment mechanism is based on the cost to hospitals for the new medical service or technology. For discharges occurring before October 1, 2019, under § 412.88, if the costs of the discharge (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare made an add-on payment equal to the lesser of: (1) 50 percent of the costs of the new medical service or technology; or (2) 50 percent of the amount by which the costs of the case exceed the standard DRG payment.

Beginning with discharges on or after October 1, 2019, for the reasons discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42297 through 42300), we finalized an increase in the new technology add-on payment percentage, as reflected at § 412.88(a)(2)(ii). Specifically, for a new technology other than a medical product designated by FDA as a QIDP, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 65 percent of the costs of the new medical service or technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment. For a new technology that is a medical product designated by FDA as a QIDP, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. As set forth in § 412.88(b)(2), unless the discharge qualifies for an outlier payment, the additional Medicare payment will be limited to the full MS–DRG payment plus 65 percent (or 75 percent for a medical product designated by FDA as a QIDP) of the estimated costs of the new technology or medical service.

We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42297 through 42300) for complete discussion on the increase in the new technology add on payment beginning with discharges on or after October 1, 2019. We note, in section II.F.9.c. of this preamble, we are proposing an increase in the new technology add-on payment percentage to 75 percent for products approved under FDA's LPAD pathway. (We refer the reader to section II.F.9.c. of this preamble below for a complete discussion regarding this proposal.)

Section 503(d)(2) of Public Law 108–173 provides that there shall be no reduction or adjustment in aggregate payments under the IPPS due to add-on payments for new medical services and technologies. Therefore, in accordance with section 503(d)(2) of Public Law 108–173, add-on payments for new medical services or technologies for FY 2005 and subsequent years have not been subjected to budget neutrality.

e. Evaluation of Eligibility Criteria for New Medical Service or Technology Applications

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we modified our regulations at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. That is, we first determine whether a medical service or technology meets the newness criterion, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We amended § 412.87(c) to specify that all applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. We note, in section II.F.9.c. of this preamble, we are proposing a process by which a technology for which an application for new technology add-on payments is submitted under the alternative pathway for certain antimicrobial products would receive conditional approval for such payment, provided the product receives FDA marketing authorization by July 1 of the year for which the new technology add-on payment application was submitted. (We refer the reader to section II.F.9.c. of this preamble below for a complete discussion regarding this proposal.)

f. Council on Technology and Innovation (CTI)

The Council on Technology and Innovation at CMS oversees the agency's cross-cutting priority on coordinating coverage, coding and payment processes for Medicare with respect to new technologies and procedures, including new drug therapies, as well as promoting the exchange of information on new technologies and medical services between CMS and other entities. The CTI, composed of senior CMS staff and clinicians, was established under section 942(a) of Public Law 108–173. The Council is co-chaired by the Director of the Center for Clinical Standards and Quality (CCSQ) and the Director of the Center for Medicare (CM), who is also designated as the CTI's Executive Coordinator.

The specific processes for coverage, coding, and payment are implemented by CM, CCSQ, and the local Medicare Administrative Contractors (MACs) (in the case of local coverage and payment decisions). The CTI supplements, rather than replaces, these processes by working to assure that all of these activities reflect the agency-wide priority to promote high-quality, innovative care. At the same time, the CTI also works to streamline, accelerate, and improve coordination of these processes to ensure that they remain up to date as new issues arise. To achieve its goals, the CTI works to streamline and create a more transparent coding and payment process, improve the quality of medical decisions, and speed patient access to effective new treatments. It is also dedicated to supporting better decisions by patients and doctors in using Medicare-covered services through the promotion of better evidence development, which is critical for improving the quality of care for Medicare beneficiaries.

To improve the understanding of CMS' processes for coverage, coding, and payment and how to access them, the CTI has developed an ''Innovator's Guide'' to these processes. The intent is to consolidate this information, much of which is already available in a variety of CMS documents and in various places on the CMS website, in a user friendly format. This guide was published in 2010 and is available on the CMS website at: *https://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/Downloads/Innovators-Guide-Master-7-23-15.pdf*.

As we indicated in the FY 2009 IPPS final rule (73 FR 48554), we invite any product developers or manufacturers of new medical services or technologies to contact the agency early in the process of product development if they have questions or concerns about the evidence that would be needed later in the development process for the agency's coverage decisions for Medicare.

The CTI aims to provide useful information on its activities and initiatives to stakeholders, including Medicare beneficiaries, advocates, medical product manufacturers, providers, and health policy experts. Stakeholders with further questions about Medicare's coverage, coding, and payment processes, or who want further guidance about how they can navigate these processes, can contact the CTI at *CTI@cms.hhs.gov*.

g. Application Information for New Medical Services or Technologies

Applicants for add-on payments for new medical services or technologies for FY 2022 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement (unless the application is under one of the alternative pathways as previously described), along with a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Complete application information, along with final deadlines for submitting a full application, will be posted as it becomes available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html*. To allow interested parties to identify the new medical services or technologies under review before the publication of the proposed rule for FY 2022, the CMS website also will post the tracking forms completed by each applicant. We note that the burden associated with this information collection requirement is the time and effort required to collect and submit the data in the formal request for add-on payments for new medical services and technologies to CMS. The aforementioned burden is subject to the PRA and approved under OMB control number 0938–1347.

As discussed previously, in the FY 2020 IPPS/LTCH PPS final rule, we adopted an alternative inpatient new technology add-on payment pathway for certain transformative new devices and for Qualified Infectious Disease Products, as set forth in the regulations at § 412.87(c) and (d). The change in burden associated with these changes to the new technology add-on payment application process were discussed in a revision of the information collection requirement (ICR) request currently approved under OMB control number 0938–1347. In accordance with the implementing regulations of the PRA, we detailed the revisions of the ICR and published the required 60-day notice on August 15, 2019 (84 FR 41723) and 30-day notice on December 17, 2019 (84 FR 68936) to solicit public comments. The ICR is currently pending OMB approval.

2. Public Input Before Publication of a Notice of Proposed Rulemaking on Add-On Payments

Section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of

Public Law 108–173, provides for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a substantial clinical improvement or advancement. The process for evaluating new medical service and technology applications requires the Secretary to—

- Provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries;
- Make public and periodically update a list of the services and technologies for which applications for add-on payments are pending;
- Accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial clinical improvement; and
- Provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new medical service or technology represents a substantial clinical improvement to the clinical staff of CMS.

In order to provide an opportunity for public input regarding add-on payments for new medical services and technologies for FY 2021 prior to publication of this FY 2021 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on October 8, 2019 (84 FR 53732), and held a town hall meeting at the CMS Headquarters Office in Baltimore, MD, on December 16, 2019. In the announcement notice for the meeting, we stated that the opinions and presentations provided during the meeting would assist us in our evaluations of applications by allowing public discussion of the substantial clinical improvement criterion for the FY 2021 new medical service and technology add-on payment applications before the publication of the FY 2021 IPPS/LTCH PPS proposed rule.

Approximately 100 individuals registered to attend the town hall meeting in person, while additional individuals listened over an open telephone line. We also live-streamed the town hall meeting and posted the morning and afternoon sessions of the town hall on the CMS YouTube web page at: *https://www.youtube.com/watch?v=4z1AhEuGHqQ* and *https://www.youtube.com/watch?v=m26Xj1EzbIY*, respectively. We considered each applicant's presentation made at the town hall meeting, as well as written comments submitted on the applications that were received by the due date of January 3, 2020, in our evaluation of the new technology add-on payment applications for FY 2021 in the development of this FY 2021 IPPS/LTCH PPS proposed rule.

In response to the published notice and the December 16, 2019 New Technology Town Hall meeting, we received written comments regarding the applications for FY 2021 new technology add-on payments. We note that we do not summarize comments that are unrelated to the ''substantial clinical improvement'' criterion. As explained earlier and in the **Federal Register** notice announcing the New Technology Town Hall meeting (84 FR 53732 through 53734), the purpose of the meeting was specifically to discuss the substantial clinical improvement criterion in regard to pending new technology add-on payment applications for FY 2021. Therefore, we are not summarizing those written comments in this proposed rule that are unrelated to the substantial clinical improvement criterion. In section II.F.5. of the preamble of this proposed rule, we are summarizing comments regarding individual applications, or, if applicable, indicating that there were no comments received in response to the New Technology Town Hall meeting notice or New Technology Town Hall meeting, at the end of each discussion of the individual applications.

3. ICD–10–PCS Section ''X'' Codes for Certain New Medical Services and Technologies

As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49434), the ICD–10–PCS includes a new section containing the new Section ''X'' codes, which began being used with discharges occurring on or after October 1, 2015. Decisions regarding changes to ICD–10–PCS Section ''X'' codes will be handled in the same manner as the decisions for all of the other ICD–10–PCS code changes. That is, proposals to create, delete, or revise Section ''X'' codes under the ICD–10–PCS structure will be referred to the ICD–10 Coordination and Maintenance Committee. In addition, several of the new medical services and technologies that have been, or may be, approved for new technology add-on payments may now, and in the future, be assigned a Section ''X'' code within the structure of the ICD–10–PCS. We posted ICD–10–PCS Guidelines on the CMS website at: *http://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-PCS-and-GEMs.html*, including guidelines for ICD–10–PCS Section ''X'' codes. We encourage providers to view the material provided on ICD–10–PCS Section ''X'' codes.

4. Proposed FY 2021 Status of Technologies Approved for FY 2020 New Technology Add-On Payments

In this section of the proposed rule, we discuss the proposed FY 2021 status of 18 technologies approved for FY 2020 new technology add-on payments. In general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. We refer readers to a table at the end of this section summarizing for FY 2021 the name of each technology, newness start date, whether we are proposing to continue or discontinue the add-on payment for FY 2021, relevant final rule citations, proposed maximum add-on payment amount and coding assignments.

a. KYMRIAH® (Tisagenlecleucel) and YESCARTA® (Axicabtagene Ciloleucel)

Two manufacturers, Novartis Pharmaceuticals Corporation and Kite Pharma, Inc., submitted separate applications for new technology add-on payments for FY 2019 for KYMRIAH® (tisagenlecleucel) and YESCARTA® (axicabtagene ciloleucel), respectively. Both of these technologies are CD–19-directed T-cell immunotherapies used for the purposes of treating patients with aggressive variants of non-Hodgkin lymphoma (NHL). On May 1, 2018, Novartis Pharmaceuticals Corporation received FDA approval for KYMRIAH®'s second indication, the treatment of adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma. On October 18, 2017, Kite Pharma, Inc. received FDA approval for the use of YESCARTA® indicated for the treatment of adult patients with r/r large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. With respect to the newness criterion, because potential cases representing patients who may be eligible for treatment using KYMRIAH® and YESCARTA® would group to the same

MS–DRGs (because the same ICD–10–CM diagnosis codes and ICD–10–PCS procedures codes are used to report treatment using either KYMRIAH® or YESCARTA®), and because we believed that these technologies are intended to treat the same or similar disease in the same or similar patient population, and are purposed to achieve the same therapeutic outcome using the same or similar mechanism of action, we considered these two technologies to be substantially similar to each other. We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41285 through 41286) and FY 2020 IPPS/LTCH/PPS final rule (84 FR 42185 through 42187) for a complete discussion. We stated in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41285 through 41286) and FY 2020 IPPS/LTCH PPS final rule (84 FR 42185 through 42186) that in accordance with our policy, since we consider the technologies to be substantially similar to each other, it is appropriate to use the earliest market availability date submitted as the beginning of the newness period for both technologies. According to the applicant for YESCARTA®, the first commercial shipment of YESCARTA® was received by a certified treatment center on November 22, 2017. Therefore, based on our policy, with regard to both technologies, we stated that the beginning of the newness period would be November 22, 2017. KYMRIAH® and YESCARTA® were approved for new technology add-on payments for FY 2019 (83 FR 41299). We refer readers to section II.H.5.a. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41283 through 41299) and section II.H.4.d. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42185 through 42187) for a complete discussion of the new technology add-on payment application, coding and payment amount for KYMRIAH® and YESCARTA® for FY 2019 and FY 2020.

Our policy is that a medical service or technology may continue to be considered ''new'' for purposes of new technology add-on payments within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology. Our practice has been to begin and end new technology add-on payments on the basis of a fiscal year, and we have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the new technology add-on payment for an additional fiscal year. In general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the fiscal year (70 FR 47362).

With regard to the newness criterion for KYMRIAH® and YESCARTA®, as discussed in the FY 2019 IPPS/LTCH PPS final rule, according to the applicant for YESCARTA®, the first commercial shipment of YESCARTA® was received by a certified treatment center on November 22, 2017. As previously stated, we use the earliest market availability date submitted as the beginning of the newness period for both KYMRIAH® and YESCARTA®. Therefore, we consider the beginning of the newness period for both KYMRIAH® and YESCARTA® to commence November 22, 2017. Because the 3-year anniversary date of the entry of the technology onto the U.S. market (November 22, 2020) will occur in the first half of FY 2021, we are proposing to discontinue new technology add-on payments for this technology for FY 2021. We are inviting public comments on our proposal to discontinue new technology add-on payments for KYMRIAH® and YESCARTA® for FY 2021.

As discussed in section II.D.2.b. of the preamble of this proposed rule, currently procedures involving CAR T-cell therapies are identified with ICD–10–PCS procedure codes XW033C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3) and XW043C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3), which became effective October 1, 2017. As discussed in section II.D.2.b. of the preamble of this proposed rule, we are proposing to create a new MS–DRG 018 for cases reporting ICD–10–PCS procedure codes XW033C3 or XW043C3 for FY 2021. We also refer readers to section II.F.5.i of the preamble of this proposed rule for a complete discussion of our proposal that, effective for FY 2022, for applications for new technology add-on payments and for previously approved technologies that may continue to receive new technology add-on payments, the proposed threshold for the upcoming fiscal year for a proposed new MS–DRG would be used to evaluate the cost criterion for any new technologies that would be assigned to a proposed new MS–DRG. As we also discuss in section II.F.5.i. of the preamble of this proposed rule, in light of the significant variance in the threshold amount for proposed new MS–DRG 018 for cases involving CAR T-cell therapies, we are proposing to apply this policy in evaluating the CAR T-cell therapy technologies for FY 2021 new technology add-on payments. This would include both the new FY 2021 CAR T-cell therapy applications, KTE–X19 and Liso-cel, and those CAR T-cell therapy technologies previously approved for new technology add-on payments, KYMRIAH® and YESCARTA®. Therefore, even if KYMRIAH® and/or YESCARTA® were still considered new and within the 3-year anniversary date of the entry of the technology onto the U.S. market, in determining whether these technologies would continue to be eligible for the new technology add-on payment, we are proposing to evaluate whether they meet the cost criterion using the proposed threshold for the proposed new MS–DRG 018 for FY 2021 payment. We refer readers to section II.F.5.i. of the preamble of this proposed rule for a complete discussion on our proposal to use the proposed threshold for proposed new MS–DRG 018 to evaluate the cost criterion for CAR T-cell therapy technologies for purposes of FY 2021 new technology add-on payments.

Per the applicants' cost analyses in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41291), the final inflated average case-weighted standardized charge per case for KYMRIAH® and YESCARTA® is $39,723 (not including the charges related to the technology) and $118,575 (not including the charges related to the technology), respectively. However, we now have cases involving the use of CAR T-cell therapy within the FY 2019 MedPAR data that we believe represent cases that would be eligible for KYMRIAH® and YESCARTA® and which can be used to estimate the average standardized charge per case for purposes of this proposed rule. This charge information from the FY 2019 MedPAR data can be found in the FY 2021 Proposed Before Outliers Removed (BOR) File (available on the CMS website) for Version 38 of the MS–DRGs. Based on information from the FY 2021 Proposed BOR File for Version 38 of the MS–DRGs, the standardized charge per case for MS–DRG 018 is $913,224. The average case-weighted threshold amount based on the proposed new MS–DRG 018 is $1,237,393. Because this estimated average case-weighted standardized charge per case for KYMRIAH® and YESCARTA® ($913,224) does not exceed the average case-weighted threshold amount for proposed new MS–DRG 018 ($1,237,393), we do not

believe that the technology would meet the cost criterion and, as previously stated, are proposing to discontinue new technology add-on payments for this technology for FY 2021. We are inviting public comment on our proposals.

b. VYXEOS™ (Daunorubicin and Cytarabine) Liposome for Injection

Jazz Pharmaceuticals, Inc. submitted an application for new technology add-on payments for the VYXEOS™ technology for FY 2019. VYXEOS™ was approved by FDA on August 3, 2017, for the treatment of adults with newly diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML–MRC). CMS approved VYXEOS™ for new technology add on payments for FY 2019 (83 FR 41299). We refer readers to section II.H.5.b. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41299 through 41305) and section II.H.4.e. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42187 through 42188) for a complete discussion of the new technology add on payment application, coding, and payment amount for VYXEOS™ for FY 2019 and FY 2020.

With regard to the newness criterion for VYXEOS™, we consider the beginning of the newness period to commence when VYXEOS™ was approved by the FDA (August 3, 2017). Because the 3-year anniversary date of the entry of the VYXEOS™ onto the U.S. market (August 3, 2020) will occur in FY 2020, we are proposing to discontinue new technology add-on payments for this technology for FY 2021. We are inviting public comments on our proposal to discontinue new technology add-on payments for VYXEOS™ for FY 2021.

c. VABOMERE™≤ (Meropenem and Vaborbactam)

Melinta Therapeutics, Inc., submitted an application for new technology add-on payments for VABOMERE™ for FY 2019. VABOMERE™ is indicated for use in the treatment of adult patients who have been diagnosed with complicated urinary tract infections (cUTIs), including pyelonephritis caused by designated susceptible bacteria. VABOMERE™ received FDA approval on August 29, 2017 and was approved for new technology add on payments for FY 2019 (83 FR 41311). We refer readers to section II.H.5.c. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41305 through 41311) and section II.H.4.f. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42188 through 42189) for a complete discussion of the new technology add on payment application, coding, and payment amount for VABOMERE™ for FY 2019 and FY 2020.

With regard to the newness criterion for VABOMERE™, we consider the beginning of the newness period to commence when VABOMERE™ received FDA approval (August 29, 2017). Because the 3-year anniversary date of the entry of VABOMERE™ onto the U.S. market (August 29, 2020) will occur in FY 2020, we are proposing to discontinue new technology add-on payments for this technology for FY 2021. We are inviting public comments on our proposal to discontinue new technology add-on payments for VABOMERE™ for FY 2021.

d. Remedē® System

Respicardia, Inc. submitted an application for new technology add-on payments for the remedē® System for FY 2019. The remedē® System is indicated for use as a transvenous phrenic nerve stimulator in the treatment of adult patients who have been diagnosed with moderate to severe central sleep apnea (CSA). On October 6, 2017, the remedē® System was approved by FDA. The remedē® System was approved for new technology add on payments for FY 2019. We refer readers to section II.H.5.d. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41311 through 41320) and section II.H.4.g. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42189 through 42190) for a complete discussion of the new technology add on payment application, coding and payment amount for the remedē® System for FY 2019 and FY 2020.

With regard to the newness criterion for the remedē® System, as we have discussed in prior rulemaking, we consider the beginning of the newness period to commence when the remedē® System was approved by FDA on October 6, 2017. However, as we summarized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42189 through 42190), a commenter on the FY 2020 IPPS/LTCH PPS proposed rule, who was also the applicant, believed that the newness period for the remedē® System should start on February 1, 2018, instead of the FDA approval date of October 6, 2017. The commenter stated that due to the required build out of operational and commercial capabilities, the remedē® System was not commercially available upon FDA approval and the first case involving its use did not occur until February 1, 2018. The commenter asserted that the date of the first implant should mark the start of the newness period since before that, the technology was not commercially available. In response to that comment, we indicated that we would consider the additional information the applicant provided when proposing whether to continue new technology add-on payments for the remedē® System for FY 2021.

As we have discussed in prior rulemaking (77 FR 53348), generally, our policy is to begin the newness period on the date of FDA approval or clearance or, if later, the date of availability of the product on the U.S. market. With regard to the commenter's assertion that the date of the first implant should mark the start of the newness period, we note that while we may consider a documented delay in a technology's availability on the U.S. market in determining when the newness period begins, under our historical policy, we do not consider how frequently the medical service or technology has been used in our determination of newness (70 FR 47349). Without additional information from the applicant, we cannot determine a newness date based on such a documented delay in commercial availability (and not the first case involving use of the remedē® System on February 1, 2018). However, even if we were to consider the newness period to commence on February 1, 2018, as recommended by the commenter, such that the 3-year anniversary date of the entry of the remedē® System onto the U.S. market would be February 1, 2021 rather than October 6, 2020, that 3-year anniversary date would still occur within the first half of FY 2021. Because the 3-year anniversary date of the entry of the remedē® System onto the U.S. market will occur in the first half of FY 2021, we are proposing to discontinue new technology add-on payments for this technology for FY 2021. We are inviting public comments on our proposal to discontinue new technology add-on payments for the remedē® System for FY 2021.

e. ZEMDRI™ (Plazomicin)

Achaogen, Inc. submitted an application for new technology add-on payments for ZEMDRI™ (plazomicin) for FY 2019. According to the applicant, ZEMDRI™ is a next generation aminoglycoside antibiotic, which has been found in vitro to have enhanced activity against many multidrug resistant (MDR) gram-negative bacteria. The applicant received approval from FDA on June 25, 2018, for use in the treatment of adults who have been diagnosed with cUTIs, including pyelonephritis. ZEMDRI™ was

approved for new technology add on payments for FY 2019 (83 FR 41334). We refer readers to section II.H.5.f. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41326 through 41334) and section II.H.4.h. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42190 through 42191) for a complete discussion of the new technology add on payment application, coding and payment amount for ZEMDRI™ for FY 2019 and FY 2020.

With regard to the newness criterion for ZEMDRI™, we consider the beginning of the newness period to commence when ZEMDRI™ was approved by FDA on June 25, 2018. As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. Because the 3-year anniversary date of the entry of ZEMDRI™ onto the U.S. market (June 25, 2021) will occur in the second half of FY 2021, we are proposing to continue new technology add-on payments for this technology for FY 2021. We are proposing that the maximum new technology add-on payment amount for a case involving the use of ZEMDRI™ would remain at $4,083.75 for FY 2021 (we refer readers to the FY 2020 IPPS/LTCH PPS final rule for complete discussion of the calculation of the new technology add on payment amount for ZEMDRI™). Cases involving ZEMDRI™ that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure codes XW033G4 (Introduction of Plazomicin anti-infective into peripheral vein, percutaneous approach, new technology group 4) or XW043G4 (Introduction of Plazomicin antiinfective into central vein, percutaneous approach, new technology group 4). We are inviting public comments on our proposal to continue new technology add-on payments for ZEMDRI™ for FY 2021.

f. GIAPREZA™ (Angiotensin II)

The La Jolla Pharmaceutical Company submitted an application for new technology add-on payments for GIAPREZA™ for FY 2019. GIAPREZA™, a synthetic human angiotensin II, is administered through intravenous infusion to raise blood pressure in adult patients who have been diagnosed with septic or other distributive shock. GIAPREZA™ was granted a Priority Review designation under FDA's expedited program and received FDA approval on December 21, 2017, for the use in the treatment of adults who have been diagnosed with septic or other distributive shock as an intravenous infusion to increase blood pressure. GIAPREZA™ was approved for new technology add on payments for FY 2019 (83 FR 41342). We refer readers to section II.H.5.g. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41334 through 41342) and section II.H.4.i. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42191) for a complete discussion of the new technology add on payment application, coding and payment amount for GIAPREZA™ for FY 2019 and FY 2020.

With regard to the newness criterion for GIAPREZA™, we consider the beginning of the newness period to commence when GIAPREZA™ was approved by FDA (December 21, 2017). As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. Because the 3-year anniversary date of the entry of GIAPREZA™ onto the U.S. market (December 21, 2020) will occur in the first half of FY 2021, we are proposing to discontinue new technology add-on payments for this technology for FY 2021. We are inviting public comments on our proposal to discontinue new technology add-on payments for GIAPREZA™ for FY 2021.

g. Cerebral Protection System (Sentinel® Cerebral Protection System)

Claret Medical, Inc. submitted an application for new technology add-on payments for the Cerebral Protection System (Sentinel® Cerebral Protection System) for FY 2019. According to the applicant, the Sentinel Cerebral Protection System is indicated for the use as an embolic protection (EP) device to capture and remove thrombus and debris while performing transcatheter aortic valve replacement (TAVR) procedures. The device is percutaneously delivered via the right radial artery and is removed upon completion of the TAVR procedure. The De Novo request for the Sentinel® Cerebral Protection System was granted by FDA on June 1, 2017. The Sentinel Cerebral Protection System was approved for new technology add on payments for FY 2019 (83 FR 41348). We refer readers to section II.H.5.h. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41342 through 41348) and section II.H.4.j. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42191 through 42192) for a complete discussion the new technology add on payment application, coding, and payment amount for the Sentinel® Cerebral Protection System for FY 2019 and FY 2020.

With regard to the newness criterion for the Sentinel® Cerebral Protection System, we consider the beginning of the newness period to commence when FDA granted the De Novo request for the Sentinel® Cerebral Protection System (June 1, 2017). Because the 3-year anniversary date of the entry of the Sentinel® Cerebral Protection System onto the U.S. market (June 1, 2020) will occur in FY 2020, we are proposing to discontinue new technology add-on payments for this technology for FY 2021. We are inviting public comments on our proposal to discontinue new technology add-on payments for the Sentinel® Cerebral Protection System for FY 2021.

h. The AQUABEAM System (Aquablation)

PROCEPT BioRobotics Corporation submitted an application for new technology add-on payments for the AQUABEAM System (Aquablation) for FY 2019. According to the applicant, the AQUABEAM System is indicated for the use in the treatment of patients experiencing lower urinary tract symptoms caused by a diagnosis of benign prostatic hyperplasia (BPH). FDA granted the AQUABEAM System's De Novo request on December 21, 2017, for use in the resection and removal of prostate tissue in males suffering from lower urinary tract symptoms (LUTS) due to benign prostatic hyperplasia. The AQUABEAM System was approved for new technology add on payments for FY 2019 (83 FR 41355). We refer readers to section II.H.5.i. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41348 through 41355) and section II.H.4.k. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42192 through 42193) for a complete discussion of the new technology add on payment application, coding, and payment for the AQUABEAM System for FY 2019 and FY 2020.

With regard to the newness criterion for the AQUABEAM System, we consider the beginning of the newness period to commence on the date FDA granted the De Novo request (December 21, 2017). As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. Because the 3-year anniversary date of the entry of the AQUABEAM System

onto the U.S. market (December 21, 2020) will occur in the first half of FY 2021, we are proposing to discontinue new technology add-on payments for this technology for FY 2021. We are inviting public comments on our proposal to discontinue new technology add-on payments for the AQUABEAM System for FY 2021.

i. AndexXa™ (Coagulation Factor Xa (Recombinant), Inactivated-zhzo)

Portola Pharmaceuticals, Inc. (Portola) submitted an application for new technology add-on payments for FY 2019 for the use of AndexXa™ (coagulation factor Xa (recombinant), inactivated-zhzo). AndexXa™ received FDA approval on May 3, 2018, and is indicated for use in the treatment of patients who are receiving treatment with rivaroxaban and apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. AndexXa™ was approved for new technology add on payments for FY 2019 (83 FR 41362). We refer readers to section II.H.5.j. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41355 through 41362) and section II.H.4.k. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42193 through 42194) for a complete discussion of the new technology add on payment application, coding, and payment amount for AndexXa™ for FY 2019 and FY 2020.

With regard to the newness criterion for AndexXa™, we consider the beginning of the newness period to commence when AndexXa™ received FDA approval (May 3, 2018). As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. Because the 3-year anniversary date of the entry of AndexXa™ onto the U.S. market (May 3, 2021) will occur in the second half of FY 2021, we are proposing to continue new technology add-on payments for this technology for FY 2021. We are proposing that the maximum new technology add-on payment for a case involving AndexXa™ would remain at $18,281.25 for FY 2021 (we refer readers to the FY 2020 IPPS/LTCH PPS final rule for complete discussion of the calculation of the new technology add on payment amount for AndexXa™). Cases involving the use of AndexXa™ that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure codes XW03372 (Introduction of inactivated coagulation factor Xa into peripheral vein, percutaneous approach, new technology group 2) or XW04372 (Introduction of inactivated coagulation factor Xa into central vein, percutaneous approach, new technology group 2). We are inviting public comments on our proposal to continue new technology add-on payments for AndexXa™ for FY 2021.

j. AZEDRA® (Iobenguane Iodine-131) Solution

Progenics Pharmaceuticals, Inc. submitted an application for new technology add-on payments for AZEDRA® (iobenguane Iodine-131) for FY 2020. AZEDRA® is a drug solution formulated for intravenous (IV) use in the treatment of patients who have been diagnosed with obenguane avid malignant and/or recurrent and/or unresectable pheochromocytoma and paraganglioma (PPGL). AZEDRA was approved by FDA on July 30, 2018, as a radioactive therapeutic agent indicated for the treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy. AZEDRA® was approved for new technology add on payments for FY 2020. We refer readers to section II.H.5.a. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42194 through 42201) for a complete discussion of the new technology add on payment application, coding and payment amount for AZEDRA® for FY 2020.

With regard to the newness criterion for AZEDRA®, we consider the beginning of the newness period to commence when AZEDRA® was approved by FDA (July 30, 2018). As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. Because the 3-year anniversary date of the entry of AZEDRA® onto the U.S. market (July 30, 2021) will occur in the second half of FY 2021, we are proposing to continue new technology add-on payments for this technology for FY 2021. We are proposing that the maximum new technology add-on payment for a case involving AZEDRA® would remain at $98,150 for FY 2021 (we refer readers to the FY 2020 IPPS/LTCH PPS final rule for complete discussion of the calculation of the new technology add on payment amount for AZEDRA®). Cases involving the use of AZEDRA® that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure codes XW033S5 (Introduction of Iobenguane I–131 antineoplastic into peripheral vein, percutaneous approach, new technology group 5), and XW043S5 (Introduction of Iobenguane I–131 antineoplastic into central vein, percutaneous approach, new technology group 5). We are inviting public comments on our proposal to continue new technology add-on payments for AZEDRA® for FY 2021.

k. CABLIVI® (Caplacizumab-yhdp)

The Sanofi Company submitted an application for new technology add-on payments for CABLIVI® (caplacizumab-yhdp) for FY 2020. The applicant described CABLIVI® as a humanized bivalent nanobody consisting of two identical building blocks joined by a tri alanine linker, which is administered through intravenous and subcutaneous injection to inhibit microclot formation in adult patients who have been diagnosed with acquired thrombotic thrombocytopenic purpura (aTTP). CABLIVI® received FDA approval on February 6, 2019, for the treatment of adult patients with acquired aTTP, in combination with plasma exchange and immunosuppressive therapy. CABLIVI® was approved for new technology add on payments for FY 2020. We refer readers to section II.H.5.b. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42201 through 42208) for a complete discussion of the new technology add on payment application, coding, and payment amount for CABLIVI® for FY2020.

With regard to the newness criterion for CABLIVI®, we consider the beginning of the newness period to commence when CABLIVI® was approved by FDA (February 6, 2019). Because the 3-year anniversary date of the entry of CABLIVI® onto the U.S. market (February 6, 2022) will occur after FY 2021, we are proposing to continue new technology add-on payments for this technology for FY 2021. We are proposing that the maximum new technology add-on payment for a case involving CABLIVI® would remain at $33,215 for FY 2021 (we refer readers to the FY 2020 IPPS/LTCH PPS final rule for complete discussion of the calculation of the new technology add on payment amount for CABLIVI®). Cases involving the use of CABLIVI® that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure codes XW013W5 (Introduction of Caplacizumab into subcutaneous tissue, percutaneous approach, new technology group 5), XW033W5 (Introduction of

Caplacizumab into peripheral vein, percutaneous approach, new technology group 5) and XW043W5 (Introduction of Caplacizumab into central vein, percutaneous approach, new technology group 5). We are inviting public comments on our proposal to continue new technology add-on payments for CABLIVI® for FY 2021.

l. ELZONRIS™ (Tagraxofusp-erzs)

Stemline Therapeutics submitted an application for new technology add-on payments for ELZONRIS™ for FY 2020. ELZONRIS™ (tagraxofusp-erzs) is a targeted therapy for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) administered via infusion. On December 21, 2018, the FDA approved ELZONRIS™ for the treatment of blastic plasmacytoid dendritic cell neoplasm in adults and in pediatric patients 2 years old and older. ELZONRIS™ was approved for new technology add on payments for FY 2020. We refer readers to section II.H.5.e. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42231 through 42237) for a complete discussion of the new technology add on payment application, coding and payment amount for ELZONRIS™ for FY 2020.

With regard to the newness criterion for ELZONRIS™, we consider the beginning of the newness period to commence when ELZONRIS™ was approved by FDA (December 21, 2018). Because the 3-year anniversary date of the entry of ELZONRIS™ onto the U.S. market (December 21, 2021) will occur after FY 2021, we are proposing to continue new technology add-on payments for this technology for FY 2021. We are proposing that the maximum new technology add-on payment for a case involving ELZONRIS™ would remain at $125,448.05 for FY 2021 (we refer readers to the FY 2020 IPPS/LTCH PPS final rule for complete discussion of the calculation of the new technology add on payment amount for ELZONRIS™). Cases involving the use of ELZONRIS™ that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure codes XW033Q5 (Introduction of Tagraxofusp-erzs antineoplastic into peripheral vein, percutaneous approach, new technology, group 5) and XW043Q5 (Introduction of Tagraxofusp-erzs antineoplastic into central vein, percutaneous approach, new technology group 5). We are inviting public comments on our proposal to continue new technology add-on payments for ELZONRIS™ for FY 2021.

m. Balversa™ (Erdafitinib)

Johnson & Johnson Health Care Systems, Inc. (on behalf of Janssen Oncology, Inc.) submitted an application for new technology add-on payments for Balversa™ for FY 2020. Balversa™ is indicated for the second line treatment of adult patients who have been diagnosed with locally advanced or metastatic urothelial carcinoma whose tumors exhibit certain fibroblast growth factor receptor (FGFR) genetic alterations as detected by an FDA-approved test, and who have disease progression during or following at least one line of prior chemotherapy including within 12 months of neoadjuvant or adjuvant chemotherapy. Balversa™ received FDA approval on April 12, 2019. Balversa™ was approved for new technology add on payments for FY 2020. We refer readers to section II.H.5.f. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42237 through 42242) for a complete discussion of the new technology add on payment application, coding and payment amount for Balversa™ for FY 2020.

With regard to the newness criterion for Balversa™, we consider the beginning of the newness period to commence when Balversa™ was approved by FDA (April 12, 2019). Because the 3-year anniversary date of the entry of Balversa™ onto the U.S. market (April 12, 2022) will occur after FY 2021, we are proposing to continue new technology add-on payments for this technology for FY 2021. We are proposing that the maximum new technology add-on payment for a case involving Balversa™ would remain at $3,563.23 for FY 2021 (we refer readers to the FY 2020 IPPS/LTCH PPS final rule for complete discussion of the calculation of the new technology add on payment amount for Balversa™). Cases involving the use of Balversa™ that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure code XW0DXL5 (Introduction of Erdafitinib antineoplastic into mouth and pharynx, external approach, new technology group 5). We are inviting public comments on our proposal to continue new technology add-on payments for Balversa™ for FY 2021.

n. ERLEADA™ (Apalutamide)

Johnson & Johnson Health Care Systems Inc., on behalf of Janssen Products, LP, Inc., submitted an application for new technology add-on payments for ERLEADA™ (apalutamide) for FY 2020. This oral drug is an androgen receptor inhibitor indicated for the treatment of patients who have been diagnosed with non-metastatic castration-resistant prostate cancer (nmCRPC). ERLEADA™ received FDA approval on February 14, 2018. ERLEADA™ was approved for new technology add on payments for FY 2020. We refer readers to section II.H.5.g. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42242 through 42247) for a complete discussion of the new technology add on payment application, coding and payment amount for ERLEADA™ for FY 2020.

With regard to the newness criterion for ERLEADA™, we consider the beginning of the newness period to commence when ERLEADA™ was approved by FDA (February 14, 2018). As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year. Because the 3-year anniversary date of the entry of ERLEADA™ onto the U.S. market (February 14, 2021) will occur in the first half of FY 2021, we are proposing to discontinue new technology add-on payments for this technology for FY 2021. We are inviting public comments on our proposal to discontinue new technology add-on payments for ERLEADA™ for FY 2021.

o. SPRAVATO™ (Esketamine)

Johnson & Johnson Health Care Systems, Inc., on behalf of Janssen Pharmaceuticals, Inc., submitted an application for new technology add-on payments for SPRAVATO™ (Esketamine) nasal spray for FY 2020. The FDA-approved indication for SPRAVATO™ is treatment resistant depression (TRD). SPRAVATO™ Nasal Spray was approved by FDA March 5, 2019. SPRAVATO™ was approved for new technology add on payments for FY 2020. We refer readers to section II.H.5.h. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42247 through 42256) for a complete discussion of the new technology add on payment application, coding and payment amount for SPRAVATO™ for FY 2020.

With regard to the newness criterion for SPRAVATO™, we consider the beginning of the newness period to commence when SPRAVATO™ was approved by FDA (March 5, 2019). Because the 3-year anniversary date of the entry of SPRAVATO™ onto the U.S. market (March 5, 2022) will occur after FY 2021, we are proposing to continue new technology add-on payments for

this technology for FY 2021. We are proposing that the maximum new technology add-on payment for a case involving SPRAVATO™ would remain at $1,014.79 for FY 2021 (we refer readers to the FY 2020 IPPS/LTCH PPS final rule for complete discussion of the calculation of the new technology add on payment amount for SPRAVATO™).

In the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19329), we noted that the applicant had submitted a request to the ICD–10 Coordination and Maintenance Committee for approval for a unique ICD–10–PCS procedure code to specifically identify cases involving the use of SPRAVATO™, beginning in FY 2020. As of the time of the development of the FY 2020 IPPS/LTCH PPS final rule, a unique ICD–10–PCS procedure code to specifically identify cases involving the use of SPRAVATO™ had not yet been finalized in response to the applicant's request. Therefore, we stated that cases reporting SPRAVATO™ would be identified by ICD–10–PCS procedure code 3E097GC (Introduction of other therapeutic substance into nose, via natural or artificial opening) for FY 2020. Subsequent to the FY 2020 IPPS/LTCH PPS final rule, a unique ICD–10–PCS procedure code to specifically identify cases involving the use of SPRAVATO™ was finalized, effective October 1, 2020. As a result, cases involving the use of SPRAVATO™ that are eligible for new technology add-on payments would be identified by ICD–10–PCS procedure code XW097M5 (Introduction of Esketamine Hydrochloride into nose, via natural or artificial opening, new technology group 5) for FY 2021. Because new ICD–10–PCS procedure code XW097M5 is not effective until October 1, 2020, ICD–10–PCS procedure code 3E097GC is the only code available to report the use of the SPRAVATO™ for FY 2020. For FY 2021, beginning with discharges on or after October 1, 2020, cases involving SPRAVATO™ that are eligible for new technology add-on payments will be identified using the new ICD–10–PCS procedure code XW097M5 (that is effective for FY 2021). We are inviting public comments on our proposal to continue new technology add-on payments for SPRAVATO™ for FY 2021.

p. XOSPATA® (Gilteritinib)

Astellas Pharma U.S., Inc. submitted an application for new technology add-on payments for XOSPATA® (gilteritinib) for FY 2020. XOSPATA® received FDA approval November 28, 2018 and is indicated for the treatment of adult patients who have been diagnosed with relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA approved test. XOSPATA® was approved for new technology add on payments for FY 2020. We refer readers to section II.H.5.i. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42256 through 42260) for a complete discussion of the new technology add on payment application, coding and payment amount for XOSPATA®.

With regard to the newness criterion for XOSPATA®, we consider the beginning of the newness period to commence when XOSPATA® was approved by FDA (November 28, 2018). Because the 3-year anniversary date of the entry of XOSPATA® onto the U.S. market (November 28, 2021) will occur after FY 2021, we are proposing to continue new technology add-on payments for this technology for FY 2021. We are proposing that the maximum new technology add-on payment for a case involving XOSPATA® would remain at $7,312.50 for FY 2021 (we refer readers to the FY 2020 IPPS/LTCH PPS final rule for complete discussion of the calculation of the new technology add on payment amount for XOSPATA®). Cases involving the use of XOSPATA® that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure code XW0DXV5 (Introduction of Gilteritinib antineoplastic into mouth and pharynx, external approach, new technology group 5). We are inviting public comments on our proposal to continue new technology add-on payments for XOSPATA® for FY 2021.

q. JAKAFI™ (Ruxolitinib)

Incyte Corporation submitted an application for new technology add-on payments for JAKAFI™ (ruxolitinib) for FY 2020. According to the applicant, JAK inhibition represents a therapeutic approach for the treatment of acute graft-versus-host disease (aGVHD) in patients who have had an inadequate response to corticosteroids. JAKAFI™ received FDA approval on May 24, 2019 for the treatment of steroid-refractory aGVHD in adult and pediatric patients 12 years and older. JAKAFI™ was approved for new technology add on payments for FY 2020. We refer readers to section II.H.5.k. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42265 through 42273) for a complete discussion of the new technology add on payment application, coding and payment amount for JAKAFI™ for FY 2020.

With regard to the newness criterion for JAKAFI™, we consider the beginning of the newness period to commence when JAKAFI™ was approved by FDA (May 24, 2019). Because the 3-year anniversary date of the entry of JAKAFI™ onto the U.S. market (May 24, 2022) will occur after FY 2021, we are proposing to continue new technology add-on payments for this technology for FY 2021. We are proposing that the maximum new technology add-on payment for a case involving JAKAFI™ would remain at $3,977.06 for FY 2021 (we refer readers to the FY 2020 IPPS/LTCH PPS final rule for complete discussion of the calculation of the new technology add on payment amount for JAKAFI™). Cases involving the use of JAKAFI™ that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure code XW0DXT5 (Introduction of Ruxolitinib into mouth and pharynx, external approach, new technology group 5). We are inviting public comments on our proposal to continue new technology add-on payments for JAKAFI™ for FY 2021.

r. T2Bacteria® Panel (T2Bacteria Test Panel)

T2Biosystems, Inc. submitted an application for new technology add-on payments for the T2Bacteria Test Panel (T2Bacteria® Panel) for FY 2020. The T2Bacteria® Panel received 510(k) clearance from FDA on May 24, 2018 for use as an aid in the diagnosis of bacteremia, bacterial presence in the blood, which is a precursor for sepsis. Per the FDA cleared indication, results from the T2Bacteria® Panel are not intended to be used as the sole basis for diagnosis, treatment, or other patient management decisions in patients with suspected bacteremia. Concomitant blood cultures are necessary to recover organisms for susceptibility testing or further identification, and for organisms not detected by the T2Bacteria® Panel. The T2Bacteria® Panel was approved for new technology add on payments for FY 2020. We refer readers to section II.H.5.m. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42278 through 42288) for a complete discussion of the new technology add on payment application, coding and payment amount for the T2Bacteria® Panel for FY 2020.

With regard to the newness criterion for the T2Bacteria® Panel, we consider the beginning of the newness period to commence when the T2Bacteria® Panel was cleared by FDA (May 24, 2018). As discussed previously in this section, in general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market

occurs in the latter half of the upcoming fiscal year. Because the 3-year anniversary date of the entry of the T2Bacteria® Panel onto the U.S. market (May 24, 2021) will occur in the second half of FY 2021, we are proposing to continue new technology add-on payments for this technology for FY 2021. We are proposing that the maximum new technology add-on payment for a case involving the T2Bacteria® Panel would remain at $97.50 for FY 2021 (we refer readers to the FY 2020 IPPS/LTCH PPS final rule for complete discussion of the calculation of the new technology add on payment amount for the T2Bacteria® Panel). Cases involving the use of the T2Bacteria® Panel that are eligible for new technology add-on payments are identified by ICD–10–PCS procedure code XXE5XM5 (Measurement of infection, whole blood nucleic acid-base microbial detection, new technology group 5). We are inviting public comments on our proposal to continue new technology add-on payments for the T2Bacteria® Panel for FY 2021.

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Summary Table of Proposed FY 2021 Status of Technologies Approved for FY 2020 New Technology Add-On Payments (NTAP)					
Technology	**Newness Start Date**	**Propose to Continue or Discontinue NTAP for FY 2021**	**Previous Final Rule Citations**	**Proposed Maximum NTAP Amount for FY 2021**	**Coding Used to Identify Cases Eligible for NTAP**
KYMRIAH® and YESCARTA®	November 22, 2017	Discontinue	(83 FR 41283 through 41299) and (84 FR 42185 through 42187)	None	XW033C3 or XW043C3
VYXEOS™	August 3, 2017	Discontinue	(83 FR 41299 through 41305) and (84 FR 42187 through 42188)	None	XW033B3 or XW043B3
VABOMERE™	August 29, 2017	Discontinue	(83 FR 41305 through 41311) and (84 FR 42188 through 42189)	None	XW033N5 or XW043N5 or National Drug Codes (NDC) 65293–0009–01 or 70842– 0120–01
remedē® System	October 6, 2017	Discontinue	(83 FR 41311 through 41320) and (84 FR 42189 through 42190)	None	0JH60DZ and 05H03MZ in combination with 05H33MZ or 05H43MZ
ZEMDRI™	June 25, 2018	Continue	(83 FR 41326 through 41334) and (84 FR 42190 through 42191)	$4,083.75	XW033G4 or XW043G4
GIAPREZA™	December 21, 2017	Discontinue	(83 FR 41334 through 41342) and (84 FR 42191)	None	XW033H4 or XW043H4
Sentinel® Cerebral Protection System	June 1, 2017	Discontinue	(83 FR 41342 through 41348) and (84 FR 42191 through 42192)	None	X2A5312
AQUABEAM System	December 21, 2017	Discontinue	(83 FR 41348 through 41355) and (84 FR 42192 through 42193)	None	XV508A4
AndexXa™	May 3, 2018	Continue	(83 FR 41355 through 41362) and (84 FR 42193 through 42194)	$18,281.25	XW03372 or XW04372
AZEDRA®	July 30, 2018	Continue	(84 FR 42194 through 42201)	$98,150	XW033S5 and XW043S5
CABLIVI®	February 6, 2019	Continue	(84 FR 42201 through 42208)	$33,215	XW013W5, XW033W5 and XW043W5
ELZONRIS™	December 21, 2018	Continue	(84 FR 42231 through 42237)	$125,448.05	XW033Q5 and XW043Q5
Balversa™	April 12, 2019	Continue	(84 FR 42237 through 42242)	$3,563.23	XW0DXL5
ERLEADA™	February 14, 2018	Discontinue	(84 FR 42242 through 42247)	None	XW0DXJ5
SPRAVATO™	March 5, 2019	Continue	(84 FR 42247 through 42256)	$1,014.79	XW097M5
XOSPATA®	November 28, 2018	Continue	(84 FR 42256 through 42260)	$7,312.50	XW0DXV5
JAKAFI™	May 24, 2019	Continue	(84 FR 42265 through 42273)	$3,977.06	XW0DXT5
T2Bacteria® Panel	May 24, 2018	Continue	(84 FR 42278 through 42288)	$97.50	XXE5XM5

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5. Proposed FY 2021 Applications for New Technology Add-On Payments (Traditional Pathway)

a. Accelerate Pheno Test BC kit for Use With Accelerate Pheno System

Accelerate Diagnostics, Inc. submitted an application for new technology add-on payments for the Accelerate PhenoTest™ BC kit for FY 2021. According to the applicant, the Accelerate PhenoTest™ BC kit is for use with the Accelerate Pheno™ system and is the only commercially available technology in the U.S. that provides microorganism (bacteria and yeast) identification (ID) and phenotypic (MIC-based) antimicrobial susceptibility test (AST) results for patients with bacteremia/fungemia and a positive blood culture. The applicant stated that the Accelerate Pheno™ system is a novel technology for fast diagnosis of bloodstream infection that provides these results in approximately 7 hours, as opposed to standard of care methods that typically take 2–3 days.

The applicant stated that other methods that provide phenotypic AST results such as current automated ID/AST systems, antibiotic gradient strips and disk diffusion require overnight culturing of the bacteria to produce an isolated colony of the pathogen, and therefore take 1–2 days longer than the Accelerate PhenoTest™ BC kit. The applicant explained that other isolate-based methods include matrix-assisted laser desorption/ionization time-of-flight mass spectrometry (MALDI–TOF MS) and biochemical methods which only provide identification results, but not antibiotic susceptibilities which would indicate possible drug resistance in common pathogens and the efficacy of the drugs of choice for particular infections. The applicant stated that similarly, T2 Dx Biosystems with T2 Bacterial Panel provides a rapid organism ID but does not provide antibiotic susceptibility results.

The applicant explained that the Accelerate PhenoTest™ BC kit identifies the following Gram-positive and Gram-negative bacteria and yeast utilizing fluorescent in-situ hybridization (FISH) probes targeting organism-specific ribosomal RNA sequences and tests the antimicrobial agents and resistance phenotypes in the organism(s) identified in the following table.

Gram Negative	ID	Ampicillin - Sulbactam	Piperacillin-Tazobactam	Cefepime	Ceftazidime	Ceftriaxone	Ertapenem	Meropenem	Amikacin	Gentamicin	Tobramycin	Ciprofloxacin	Aztreonam
Escherichia coli	✓	●	●	●	●	●	●	●	●	●	●	●	●
Klebsiella spp.[a]	✓	●	●	●	●	●	●	●	●	●	●	●	●
Enterobacter spp.[b]	✓		●	●	●	●	●	●	●	●	●	●	●
Proteus spp.[c]	✓	●	●	●	●	●	●	●	●	●	●	●	●
Citrobacter spp.[d]	✓		●	●	●	●	●	●	●	●	●	●	●
Serratia marcescens	✓		●	●	●	●	●	●	●	●	●	●	●
Pseudomonas aeruginosa	✓		●	●	●			●	●	●	●	●	
Acinetobacter baumannii	✓		●						●				

[a] *Klebsiella* spp. (*Klebsiella pneumoniae, Klebsiella oxytoca,* not differentiated), [b] *Enterobacter* spp. (*Enterobacter cloacae, Enterobacter aerogenes*, not differentiated), [c] *Proteus* spp. (*Proteus mirabilis, Proteus vulgaris,* not differentiated), [d] *Citrobacter* spp. (*Citrobacter freundii, Citrobacter koseri,* not differentiated)

Gram Positive	ID	Ampicillin	Ceftaroline	Erythromycin	Daptomycin	Linezolid	Vancomycin	MRSA (Cefoxitin)	MLSb (Erythromycin -Clindamycin)
Staphylococcus aureus	✓		●	●	●	●	●	●	
Staphylococcus lugdunensis	✓						●	●	●
Coagulase-negative staphylococci [e]	✓				●		●	●	●
Enterococcus faecalis	✓	●			●	●	●		
Enterococcus faecium	✓	●			●	●	●		
Streptococcus spp.[f]	✓								
Yeast									
Candida albicans	✓								
Candida glabrata	✓								

[e]Coagulase-negative *Staphylococcus* species (*Staphylococcus epidermidis*, *Staphylococcus haemolyticus*, *Staphylococcus hominis*, *Staphylococcus capitis*, *Staphylococcus lugdunensis*, *Staphylococcus warneri* not differentiated), [f]*Streptococcus* spp. (*Streptococcus mitis*, *Streptococcus oralis, Streptococcus gallolyticus*, *Streptococcus agalactiae*, *Streptococcus pneumoniae*, not differentiated)

The applicant stated that the laboratory workflow for the Accelerate PhenoTest™ BC kit is simple and requires ~2 minutes of hands on laboratory technologist time, in three steps: (1) Aliquot 0.5 mL positive blood culture into sample vial; (2) load the sample into the Accelerate PhenoTest™ BC kit; and (3) load the Accelerate PhenoTest™ BC kit into the Accelerate Pheno™ system.

The applicant explained and stated the following regarding use of the Accelerate PhenoTest™ BC kit:

- Microorganism identification (ID) is performed using fluorescence in situ hybridization (FISH). Colocalization of target (green fluorescence) and universal (red fluorescence) probe signal confirms presence and identity of the target organism while differentiating from non-specific staining. ID results are produced in approximately 2 hours. AST is performed using morphokinetic cellular analysis (MCA), which measures morphological and kinetic changes over time of organisms exposed to antibiotics.
- MCA is a computer vision-based analytical method that uses digital microscopy inputs and machine learning technology to observe individual live cells and recognize patterns of change over time. This technology tracks and analyzes multiple morphological and kinetic changes of individual cells and microcolonies under a variety of conditions. These changes include morphokinetic features such as cell morphology, mass as measured by light intensity of a growing cells, division rate, anomalous growth patterns, and heterogeneity. During this period, morphokinetic features are measured and used for analysis; the precise quantitative measurement of individual cell growth rate over time is a powerful indicator of antimicrobial efficacy. Onboard software algorithms derive minimum inhibitory concentration (MIC) values from the measured features, and apply appropriate expert rules for proper interpretation and reporting of categorical interpretations: S, I, or R (susceptible, intermediate, or resistant). According to the applicant, AST results are reported in approximately 7 hours from the start of the run.

The applicant stated that rapid ID/genotypic resistance marker tests using polymerase chain reaction (PCR) provide partial results and no MIC values. The applicant further stated that the clinically actionable results using resistant marker tests are less definitive in that the absence or presence of a resistance gene does not necessarily indicate susceptibility or resistance to an antibiotic.

According to the applicant, theoretical studies and research not conducted with the Accelerate PhenoTest™ BC kit have illustrated the strong connection between time to appropriate antimicrobial therapy and clinical outcomes for bacteremic patients. The applicant stated that time to phenotypic susceptibility results is critical for patients with serious infections as studies show a measurable increase in mortality for each hour appropriate treatment is delayed in patients with septic shock.[1] The applicant further stated that based on these and other results, guidelines from the Surviving Sepsis Campaign recommend prescribing empiric broad-spectrum antimicrobials within 1 hour of recognition for both sepsis and septic shock.[2] However, the applicant explained that initial empiric therapy can be inappropriate in as high as 30–50 percent of cases.[3] [4] The applicant stated that patients treated with appropriate versus inappropriate initial antimicrobial therapy have been shown to have improved patient outcomes including mortality, hospital length of stay (LOS), intensive care unit (ICU) LOS, and days on mechanical ventilation.[5]

With respect to the newness criterion, the Accelerate PhenoTest™ BC kit received FDA *de novo* clearance on February 23, 2017. According to applicant, the technology was on the

[1] Kumar A, et al. Duration of hypotension before initiation of effective antimicrobial therapy is the critical determinant of survival in human septic shock. *Crit Care Med* 2006; 34(6):1589–96.

[2] Rhodes A, et al. Surviving Sepsis Campaign: International Guidelines for Management of Severe Sepsis and Septic Shock: 2016. *Intensive Care Med* 2017; 43(3):304–77.

[3] Hecker MT, et al. Unnecessary Use of Antimicrobials in Hospitalized Patients. *Arch Intern Med* 2003; 163:972–8.

[4] Herzke CA, et al. Empirical Antimicrobial Therapy for Bloodstream Infection Due to Methicillin-Resistant Staphylococcus aureus: No Better Than a Coin Toss. *Infect Control Hosp Epidemiol* 2009; 30(11):1057–61.

[5] Burnham J, et al. Clinical Impact of Expedited Pathogen Identification and Susceptibility Testing for Gram-negative Bacteremia and Candidemia Using the Accelerate PhenoTM System. Poster presented at: IDWeekTM; October 2017, San Diego, CA.

market immediately after FDA approval in February 2017. According to the applicant, on September 22, 2019, Accelerate Diagnostics, Inc. (AXDX) submitted a 510(k) submission to FDA, which details several changes to the Accelerate PhenoTest™ BC kit. According to the applicant, the purpose of the 510(k) submission is to present product enhancements and include an additional organism-antimicrobial combination to the panel. There are currently no ICD–10–PCS procedure codes that uniquely identify the use of the Accelerate Pheno™ BC kit. We note the applicant submitted a request for approval for a unique ICD–10–PCS procedure code to identify use of the technology beginning in FY 2021. The applicant provided the following ICD–10 codes that they stated would identify cases for which their technology is used, in the interim.

ICD-10 Code	ICD-10 Description
A40	Streptococcal sepsis
A40.0	Sepsis due to streptococcus, group A
A40.1	Sepsis due to streptococcus, group B
A40.3	Sepsis due to *Streptococcus pneumoniae*
A40.8	Other streptococcal sepsis
A40.9	Streptococcal sepsis, unspecified
A41	Other sepsis
A41.0	Sepsis due to *Staphylococcus aureus*
A41.01	Sepsis due to methicillin susceptible *Staphylococcus aureus*
A41.02	Sepsis due to methicillin resistant *Staphylococcus aureus*
A41.1	Sepsis due to other unspecified staphylococcus
A41.2	Sepsis due to unspecified staphylococcus
A41.4	Sepsis due to anaerobes
A41.5	Sepsis due to other Gram-negative organisms
A41.51	Sepsis due to *Escherichia coli*
A41.52	Sepsis due to *Pseudomonas*
A.41.53	Sepsis due to *Serratia*
A41.59	Other Gram-negative sepsis
A41.8	Other specified sepsis
A41.81	Sepsis due to *Enterococcus*
A41.89	Other specified sepsis
A41.9	Sepsis, unspecified organism
B37.7	**Candidal** sepsis
P36	Bacterial sepsis of newborn
P36.0	Sepsis of newborn due to streptococcus, group B
P36.10	Sepsis of newborn due to unspecified streptococci
P36.19	Sepsis of newborn due to other streptococci
P36.2	Sepsis of newborn due to *Staphylococcus aureus*
P36.30	Sepsis of newborn due to unspecified staphylococci
P36.39	Sepsis of newborn due to other staphylococci
P36.4	Sepsis of newborn due to *Escherichia coli*
P36.5	Sepsis of newborn due to anaerobes
P36.8	Other bacterial sepsis of newborn
P36.9	Bacterial sepsis of newborn, unspecified
R78.81	Bacteremia
R65.2	Severe sepsis
R65.20	Severe sepsis without septic shock
R65.21	Severe sepsis with septic shock
T81.12XA	Postprocedural septic shock, initial encounter
T81.12XD	Postprocedural septic shock, subsequent encounter
T81.12XS	Postprocedural septic shock, sequela

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product used the same or similar mechanism of action to achieve a therapeutic outcome, according to the applicant, the Accelerate PhenoTest™ BC kit for use with the Accelerate Pheno™ system is the only fast, automated, phenotypic, direct-from-positive blood culture ID/AST technology available. The applicant

explained that it provides MIC values as well as SIR categorical designations (that is, susceptible, intermediate, resistant). The applicant further explained that MIC results are used to not only choose which antimicrobial(s) is/are active for a patient's infection, but also may be used to modify dosing, based on the relative degree of resistance to an antimicrobial the MIC indicates. The applicant also stated that both results are significantly faster than other methods (approximately 40 hours faster).

The applicant stated that in support of the uniqueness of the test compared to other technologies, in 2017 the Accelerate PhenoTest™ BC kit used with the Accelerate Pheno™ system was granted marketing authorization by the FDA under the *de novo* pathway, which is reserved for devices of a new type with low-to-moderate risk for which there are no legally marketed predicates.

The applicant explained that other FDA-cleared identification (ID) technologies include Bruker Daltonics MALDI TOF–MS, bioMerieux Vitek® MS. Additionally, the applicant noted several FDA-cleared AST methods, which are based on broth microdilution (BMD), including bioMerieux VITEK®2, ThermoFisher Sensititre™ AST system, BD Phoenix™ AST system, and Beckman Coulter MicroScan Walkaway. Additionally, the applicant noted that AST can be determined using antibiotic gradient strips and disk diffusion. The applicant notes all of these technologies require overnight culturing to produce an isolated colony of the pathogen, and therefore take 1 to 2 days longer than the Accelerate PhenoTest™ BC kit.

According to the applicant, FDA-cleared genotypic technologies provide organism identification results and presence/absence of some antibiotic resistance genes. The applicant explained that knowledge that a gene is present can be used to rule out therapy, but the absence of a resistance gene generally does not allow a clinician to rule-in antibiotic therapy, unlike phenotypic AST, which can do both. According to the applicant, genotypic tests that are FDA cleared and available in the US include the BioFire® FilmArray, Luminex® Verigene® Nanosphere, GenMark ePlex® BCID Panel, Curetis Unyvero A50 system, iCubate® iC-system™, T2 Dx Biosystems with T2 Bacterial Panel, and Cepheid GeneXpert® (Table 2). The applicant explained that rapid ID/genotypic resistance marker tests can provide fast results in hours directly from positive blood culture; however these methods only provide partial results, resulting in less diagnostic certainty. The applicant further explained that unlike phenotypic AST results, the absence or presence of a resistance gene does not definitively indicate susceptibility or resistance to an antibiotic, respectively. The applicant noted that resistance can be caused by multiple mutations across >1 gene (that is, porin or efflux pump), and resistance depends not only on the presence of a gene, but also on its level of expression. The applicant further explained that while clinicians can use these partial results to prescribe effective therapy in select cases, patients are often left on overly broad spectrum therapy, which may or may not be effective for that individual because the resistance marker results only allow clinicians to rule-out certain therapies.[6]

According to the applicant, in contrast, phenotypic MIC-based results are key drivers for clinical decisions when determining antibiotics, dose regimen, and de-escalation. The applicant also stated that in a recent conference publication, one institution that implemented a genotypic resistance marker test found that even after 5 years of use, clinicians did not de-escalate from empiric antimicrobials for 62 percent of patients with *E. coli* and *Klebsiella pneumoniae* bloodstream infections until phenotypic antimicrobial susceptibility results were available.[7] To address whether the version of the Accelerate PhenoTest BC kit currently pending 510(k) clearance uses the same or similar mechanism of action to achieve a therapeutic outcome as the version that has been on the market since February 2017, the applicant provided the following table describing the differences between the two products:

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[6] Dien Bard J. and Lee F. Why Can't We Just Use PCR? The Role of Genotypic versus Phenotypic Testing for Antimicrobial Resistance Testing. *Clin Microb* 40(11): 87.

[7] Mead P., Raimondi T., Farrell J. Money For Nothing—Prospective Examination of Impact of Biofire BC ID PCR on Empiric Antibiotic Treatment in Escherichia coli & Klebsiella pneumoniae Bacteremia. Poster presented at: ASM Microbe; June 2019, San Francisco, CA.

Change Category	**New** Accelerate PhenoTest™ BC Kit (K192665, pending clearance), Submitted September 22, 2019	**Predicate** Accelerate PhenoTest™ BC Kit (DEN160032), February 23, 2017
Antimicrobial Agents	Two concentrations are used to determine MIC results for antimicrobials to improve accuracy: aztreonam, cefepime, ceftazidime and piperacillin-tazobactam with *Pseudomonas aeruginosa*.	Single concentrations are used to determine MIC results for antimicrobials: aztreonam, cefepime, ceftazidime and piperacillin tazobactam.
	MLSb and erythromycin antimicrobials were removed from the AST panel due to lack of clinical significance.	MLSb and erythromycin antimicrobials were included on the AST panel.
Test Kit	The Accelerate PhenoTest™ BC kit enhanced wet reagent well was modified to consolidate wells. Smaller wells of ethanol (3 wells) SDS buffer (2 wells) and Tris buffer (7 wells) were combined into larger wells to reduce the occurrence of trapped bubbles that could cause run errors.	The original Accelerate PhenoTest™ BC kit wet reagent well is used.
External Quality Control Assays	The Accelerate PhenoTest™ BC ID and AST QC test(s) is offered in addition to the manual assay for ease of us.	A manual assay only is available for quality control testing.
ATCC Quality Control Organisms Maintenance	No quality control organism maintenance is required.	Users are required to maintain all 20 quality control strains required for testing.
QC Sample Preparation	Automated quality control inoculum preparation and standardization are performed by the Accelerate Pheno™ system.	User prepares standardized inoculum of quality control strains and manually dispenses each into designated wells in the Accelerate PhenoTest™ BC kit.

Change Category	New Accelerate PhenoTest™ BC Kit (K192665, pending clearance), Submitted September 22, 2019	Predicate Accelerate PhenoTest™ BC Kit (DEN160032), February 23, 2017
Accessories/Materials Required But Not Provided For External QC Testing	All materials are included with the automated quality control tests (Accelerate PhenoTest™ BC ID and AST QC test(s)).	Laboratories are required to provide the following additional materials not included with the product for quality control testing: - QC Assay Loading "Template Tool" - ATCC QC organism(s) - 35°C (+/- 2) Incubator with CO_2 - Trypticase soy agar (TSA) plates containing 5% sheep's blood (BAP) (for bacteria growth) - Sabouraud Dextrose plates (for yeast growth) - Commercially prepared Trypticase soy broth (TSB) with no additives - Commercially available, calibrated turbidity meter - 0.5 and 2.0 McFarland Standards for use with commercially available turbidity meter - Falcon® 5mL Round Bottom Polystyrene Test Tubes with Snap Cap, Sterile (Corning Product # 352054) or equivalent
Test Interpretation and Results Reporting	Expert rules were modified to adjust reporting and messaging for certain organism/antimicrobial combinations to maintain a high level of patient safety.	Original expert rules were used.
	ID Interpretive rules are included to increase reporting of the monomicrobial call and decrease incidence of indeterminate calls and ambiguous results due to debris/noise.	Original monomicrobial indeterminate and false positive rules were used.
	An AO Bright rule is included to improve overall reportability by decreasing invalid results.	Original invalid rules were used.
	Noise Rejection analysis decreases by-run false positive rate of clinical stock isolates to 2.1%.	The original by-run false positive rate for clinical stock isolates was 8.2%.
	Improved ID target detection algorithms are included.	Original ID target detection algorithms were used.
	Algorithm changes for the antimicrobial meropenem decrease the minor discrepancy rate (where the reference AST category results is resistant or susceptible and the Accelerate Pheno™ system is intermediate) with *Pseudomonas aeruginosa* to 5.0%.	The original minor discrepancy rate for of meropenem with *Pseudomonas aeruginosa* was 7.8%.

Change Category	New Accelerate PhenoTest™ BC Kit (K192665, pending clearance), Submitted September 22, 2019	Predicate Accelerate PhenoTest™ BC Kit (DEN160032), February 23, 2017
Time to Result	ID results are provide in ~2 hours. AST results are provided ~7 hours.	ID results were provided ~1.5 hours. AST results were provided ~6.5 hours.
Instrument	The original optical set submitted in DEN160032 is included along with an additional far-red filter to assist in detection of noise objects in the FISH ID assay.	Original optical set was used for FISH ID.
Computing System	An additional computing system is offered, Interface PC/Analysis module setup, which supports up to 8 ID/AST modules.	The original computing system was offered, Control PC/Analysis PC setup, which supports up to 4 ID/AST modules.
Software Algorithms	Software algorithms were modified to include ID interpretive rules, AO bright rule, and ID reportability improvements. Algorithms were updated to improve MIC determination for aztreonam, cefepime, ceftazidime, meropenem and piperacillin-tazobactam.	Original algorithms were used to determine MIC values for aztreonam, cefepime, ceftazidime, meropenem and piperacillin-tazobactam.
Software QC Assays	Accelerate Pheno™ system software automates QC Testing for ID and AST using the Accelerate PhenoTest™ BC ID/AST QC tests.	QC assays performed by the Accelerate Pheno™ system require manual dispensing of standardized inoculum into designated wells of the Accelerate PhenoTest™ BC kit.

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According to the applicant, while this product originally received FDA *de novo* status in February 2017, it should still be considered new for the following two reasons. First, the applicant stated that there is still no other comparable integrated rapid ID and rapid AST diagnostic for positive blood cultures commercially available in the US. The applicant stated that this technology was completely novel when it was launched and remains alone in its class today. The applicant added that this particular technology has yet to experience widespread adoption in U.S. hospitals. Second, the applicant stated that it submitted an FDA 510(k) submission on Sept. 22, 2019 for a product addendum, which contains clinically relevant modifications to the originally cleared product, impacting both the organism identification and the antibiotic susceptibility testing reportability. The applicant stated that it believes the software updates and assay changes contained in this submission, and as set forth in the previous table, are substantive and meet the criteria for newness.

With respect to the second criterion, the applicant did not indicate whether the Accelerate PhenoTest™ BC kit would be assigned to the same MS–DRGs as cases representing patients who receive diagnostic information from competing technologies, or from the version of the Accelerate PhenoTest™ BC kit that was approved in February 2017. However, we believe that cases involving the use of the technology would be assigned to the same MS–DRGs as cases involving the use of the previous version of the Accelerate PhenoTest™ BC Kit that was approved in 2017, as well as cases representing patients who receive diagnostic information from competing technologies.

With respect to the third criterion, the applicant did not specify whether the Accelerate PhenoTest™ BC kit involves the treatment of the same or similar type of disease and the same or similar patient population as existing technologies, including the version of the Accelerate PhenoTest™ BC kit that was approved in February 2017. However, we believe that both the current version of the Accelerate PhenoTest™ BC kit and the predicate version of the Accelerate PhenoTest™ BC kit, as well as competing technologies that may also aid in diagnosing patients with bloodstream infections, would treat the same or similar type of disease and patient population.

The applicant is seeking new technology add-on payments for the version of the Accelerate PhenoTest™ BC kit that is the subject of the September 2019 510(k) submission to FDA. We are concerned that this updated technology may be substantially similar to the first version of the Accelerate PhenoTest™ BC kit that was first available on the U.S. market in February 2017 and, therefore, the technology would not meet the newness criterion. It is not clear that the changes made to the product currently pending 510(k) clearance would distinguish the mechanism of action of this updated product from the mechanism of action of the first version of the technology, which received FDA *de novo* clearance on February 23, 2017. Although we understand that the updated version includes software updates and assay changes, we believe both tests may nonetheless use the same mechanism of action, consisting of phenotypic, direct-from-positive blood culture identification and AST technology that provides MIC values as well as SIR categorical designations.

Furthermore, like other available diagnostic tests, the Accelerate Phenotype™ BC Kit uses positive blood cultures to identify microorganisms.

We also are concerned with regard to the lack of information from the applicant regarding the second and third substantial similarity criteria. Because the first version of the Accelerate PhenoTest™ BC kit was first available on the U.S. market in February 2017 and because we believe the version that is currently pending 510(k) clearance may be substantially similar, we are concerned that the product may not be considered new for the purposes of new technology add-on payments. We believe the costs associated with the Accelerate PhenoTest™ BC kit should be reflected in the relative payment weights for the MS–DRGs to which cases involving treatment with the Accelerate PhenoTest™ BC kit would be assigned, because the product has been on the market and available since 2017. Also, similar to our discussion in the FY 2006 IPPS final rule (70 FR 47349), whether a technology has yet to experience widespread adoption in U.S. hospitals is not relevant to the determination of whether the technology is ''new.'' Consistent with the statute, a technology no longer qualifies as ''new'' once it is more than 2 to 3 years old, irrespective of how frequently it has been used in the Medicare population. Therefore, if a product is more than 2 to 3 years old, we consider its costs to be included in the MS–DRG relative weights whether its use in the Medicare population has been frequent or infrequent. We are inviting public comments on whether the Accelerate PhenoTest™ BC kit is substantially similar to other technologies, including the version of this technology that received FDA *de novo* clearance on February 23, 2017, and whether the Accelerate PhenoTest™ BC kit meets the newness criterion.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that the technology meets the cost criterion. The applicant identified 43 ICD–10–CM diagnosis codes that apply to conditions for which its technology may be used, and then applied these 43 codes to the MEDPAR Limited Data Set (LDS)—Hospital (National) FY 2018 (Proposed Rule) data, in order to identify cases for which the use of Accelerate PhenoTest™ BC kit could be appropriate. These diagnosis codes are the 41 diagnosis codes listed in the previous table, along with ICD–10–CM codes R78.81 (Bacteremia) and B49 (Unspecified mycosis).

According to the applicant, this process resulted in 27,971 cases spanning 411 MS–DRGs, with approximately 80 percent of those cases mapping to the following top 8 MS–DRGs:

MS-DRG	MS-DRG Title
MS–DRG 003	ECMO or Tracheostomy with MV >96 Hours or PDX Except Face, Mouth and Neck with Major O.R. Procedure
MS–DRG 314	Other Circulatory System Diagnoses with MCC
MS–DRG 698	Other Kidney and Urinary Tract Diagnoses with MCC
MS-DRG 853	Infections and Parasitic Diseases with O.R. Procedure with MCC
MS–DRG 854	Infections and Parasitic Diseases with O.R. Procedure with CC
MS-DRG 870	Septicemia or Severe Sepsis with MV >96 Hours
MS-DRG 871	Septicemia or Severe Sepsis without MV >96 Hours with MCC
MS-DRG 872	Septicemia or Severe Sepsis without MV >96 Hours without MCC

The applicant performed two analyses to demonstrate that the technology meets the cost criterion. The first analysis was based on 100 percent of the claims that included the specified ICD–10 codes, while the second analysis was based on the 80 percent of claims that mapped to the top 8 MS–DRGs listed previously.

Under both analyses, the applicant removed charges for prior technology or technology being replaced. Using Accelerate Diagnostics customer cost and utilization information and the National Average Laboratory Cost-to-Charge Ratio (CCR) of 0.109 (84 FR 42179), the applicant estimated the charge for prior technology as approximately $339. Specifically, the applicant multiplied an 80 percent utilization by a cost of $15 for the MALDI–TOF MS-based test and multiplied a 25 percent utilization by a cost of $100 for the Molecular BCID. The applicant then added these calculations, reaching a sum of $37 of estimated cost. The applicant divided this cost by the National Average Laboratory CCR (0.109), reaching an estimated charge of $339.45. The applicant also removed other charges related to the prior technology, assuming cost savings related to reduced LOS, vancomycin avoidance, *C. difficile* infection avoidance, and acute kidney injury avoidance based on data from provided studies.[8] [9] [10] [11] [12] [13] [14]

The applicant then standardized the charges and applied the 2-year outlier inflation factor of 11.1 percent used to update the outlier threshold in the FY 2020 IPPS final rule (84 FR 42629). The applicant indicated an estimated per patient cost for the Accelerate PhenoTest™ BC kit of $375.17 (based on current average sales price of the Accelerate PhenoTest™ BC kit, plus market data on several other associated elements of per-patient cost enumerated by the applicant). The applicant then added charges for the Accelerate PhenoTest™ BC kit by dividing the average hospital cost per patient of $375.17 by the National Average Laboratory CCR of 0.109.

The applicant reported that these analyses met the cost criterion in each instance. For the analysis based on 100 percent of cases, the applicant

[8] Zimlichman E, et al. Health Care-Associated Infections: A Meta-analysis of Costs and Financial Impact on the US Health Care System. JAMA Intern Med 2013; 173(22):2039–46.

[9] Chertow GM, et al. Acute kidney injury, mortality, length of stay, and costs in hospitalized patients. J Am Soc Nephrol 2005; 16:3365–70.

[10] Sheth S, et al. Impact of Rapid Identification (ID) and Antimicrobial Susceptibility Testing (AST) on Antibiotic Therapy and Outcomes for Patients with Bacteraemia/Candidaemia. Poster presented at: ECCMID; April 2019, Amsterdam, Netherlands.

[11] Henry J Kaiser Family Foundation. Hospital Adjusted Expenses per Inpatient Day by Ownership. KFF website: *https://www.kff.org/health-costs/state-indicator/expenses-per-inpatient-day-by-ownership*. Published 2016. Accessed June 6, 2019.

[12] Suryadevara M, et al. Inappropriate Vancomycin Therapeutic Drug Monitoring in Hospitalized Pediatric Patients Increases Pediatric Trauma and Hospital Costs. J Pediatr Pharmacol Ther 2012; 17(2):159–65.

[13] Zimlichman E, et al. Health Care-Associated Infections: A Meta-analysis of Costs and Financial Impact on the US Health Care System. JAMA Intern Med 2013; 173(22):2039–46.

[14] Dare R, et al. Impact of Accelerate Pheno™ Rapid Blood Culture Detection System on Laboratory and Clinical Outcomes in Bacteremic Patients. Oral presentation at: IDWeek™; October 2018, San Francisco, CA.

computed a final inflated average case weighted standardized charge per case of $107,432, as compared to an average case-weighted threshold amount of $75,101. For the analysis based on the 80 percent of cases in the top eight MS–DRGs, the applicant computed a final inflated average case weighted standardized charge per case of $86,956, as compared to the average case-weighted threshold amount of $71,401. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount under both analyses described previously, the applicant asserted that the technology meets the cost criterion.

We are inviting public comments on whether the Accelerate PhenoTest™ BC Kit meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that the Accelerate PhenoTest BC kit represents a substantial clinical improvement over existing technology because data from studies show that it offers the ability to diagnose a medical condition earlier than allowed by currently available methods. Additionally, the applicant stated that these studies suggest the Accelerate PhenoTest BC kit improves clinical outcomes relative to services or technologies previously available. Specifically, according to the applicant, the studies demonstrate a reduction in clinically significant adverse events such as lower mortality, a decrease in inappropriate therapy, a more rapid resolution, and the termination of antibiotic therapy.

The applicant submitted fifteen published peer-reviewed articles that the applicant stated demonstrate the ability to diagnose a medical condition earlier than allowed by currently available methods. Per the applicant, the results demonstrated the following: reduction in time to AST results, de-escalation or escalation, and hands-on time; decreased time to step-down therapy, initiation of definitive therapy (TTDT), optimal therapy (TTOT), effective therapy (TTET) and active therapy; and decreased use of aminopenicillin + B-lactamase, cefepime, aminoglycosides, piperacillin-tazobactam, and vancomycin. The applicant also asserted that the results demonstrated reduced length of stay, total antibiotic days on therapy (DOT), antibiotic intensity score, average number of antibiotic days, median days of broad-spectrum antibiotics, time to first antibiotic modification and first Gram negative antibiotic modification, and inpatient mortality. We summarize the studies the applicant provided as follows:

- Brazelton de Cardenas, et al.[15] is an equivalency performance (methods comparison) paper and showed identification sensitivity of 91.2 percent and AST categorical agreement (CA) of 91.2–91.8 percent. The applicant explained that the time to results for the Accelerate PhenoTest™ BC kit for use with the Accelerate Pheno™ system were 40.1 hours faster than standard of care (VITEK®2 and BMD).
- Bowler, et al.[16] is an equivalency performance paper that examined *Acinetobacter* clinical isolates showing ID sensitivity of 97.6 percent and specificity of 86.6 percent and AST essential agreement of 98.0 percent. The applicant stated that standard of care was MALDI–TOF MS for ID and broth microdilution (BMD) for AST.
- Burnham, et al.[17] is an equivalency performance paper showing ID sensitivity of 91.5 percent and specificity of 99.6 percent and AST CA of 91.0 percent. The applicant explained that the time to results for the Accelerate PhenoTest™ BC kit for use with the Accelerate Pheno™ system was 40.8 hours faster than standard of care (VITEK®2 or DD for AST).
- Charnot-Katsikas, et al.[18] is an equivalency performance paper showing ID sensitivity of 95.6 percent and specificity of 99.5 percent and AST EA of 95.1 percent and CA of 95.5 percent. The applicant explained that the time to results for the Accelerate PhenoTest™ BC kit for use with the Accelerate Pheno™ system was 41.86 hours faster than standard of care (VITEK MS for ID and VITEK2 for AST) and reduction in hands-on time was 25.5 minutes per culture.
- De Angelis, et al.[19] is an equivalency performance paper showing antimicrobial susceptibility testing (AST) categorical agreement (CA) of 92.7 percent for gram-positive and 99.0 percent for gram-negative organisms. The applicant explained that the standard of care was BMD for AST.
- Descours, et al.[20] is an equivalency performance paper showing ID sensitivity of 96.2 percent and AST EA of 92.3 percent and CA of 93.7 percent. The applicant explained that the time to results for the Accelerate PhenoTest™ BC kit for use with the Accelerate Pheno™ system was 24.4 hours faster than MALDI–TOF MS for ID and VITEK®2/traditional BMD for AST. According to the applicant, the study concluded that overall categorical agreement was decreased for beta-lactams (cefepime 84.4 percent, piperacillin-tazobactam 86.5 percent, ceftazidime 87.6 percent) or *Pseudomonas aeruginosa* (71.9 percent; with cefepime 33.3 percent, piperacillin-tazobactam 77.8 percent, ceftazidime 0 percent).
- Giordano, et al.[21] is an equivalency performance paper showing ID sensitivity of 97 percent and AST CA of 91.3 percent (breakdown of 94.7 percent gram-positive (GP) and 90.2 percent gram-negative (GN) organisms) and EA of 81.8 percent. Standard of care was MALDI–TOF MS for ID and Sensitire/traditional BMD for AST. According to the applicant, the paper concluded that both methodologies provided comparable results, showing no statistically significant differences. The study concluded that the time to obtain ID and AST as well as costs are lower for Alfred 60AST combined with MALDI–TOF MS; however, the PhenoTest BC kit provides both identification and MIC determination in one cartridge. The study noted that both systems were determined to allow for proper diagnostic stewardship in order to hinder sepsis and minimize the spread of bacterial resistance.
- Lutgring et al.[22] is an equivalency performance paper showing ID sensitivity of 94.7 percent and

[15] Brazelton de Cardenas JN, Su Y, Rodriguez A, et al. Evaluation of rapid phenotypic identification and antimicrobial susceptibility testing in a pediatric oncology center. *Diagn Microbiol Infect Dis* 2017; 89: 52–7.

[16] Bowler et al. Evaluation of the Accelerate Pheno™ System for identification of Acinetobacter clinical isolates and minocycline susceptibility testing. *J Clin Microbiol.* 2019 57(3):e01711–18.

[17] Burnham JP, Wallace MA, Fuller BM, et al. Clinical Effect of Expedited Pathogen Identification and Susceptibility Testing for Gram-Negative Bacteremia and Candidemia by Use of the Accelerate Pheno™ System. *J Appl Lab Med* 2019. 3(6):569.

[18] Charnot-Katsikas A, Tesic V, Love N, et al. Use of the Accelerate Pheno™ System for Identification and Antimicrobial Susceptibility Testing of Pathogens in Positive Blood Cultures and Impact on Time to Results and Workflow. *J Clin Microbiol* 2018; 56.

[19] De Angelis G, Posteraro B, Menchinelli G, et al. Antimicrobial susceptibility testing of pathogens isolated from blood culture: a performance comparison of Accelerate Pheno™ and VITEK®2 systems with broth microdilution method. *J Antimicrob Chemother* 2019. 74 (Supplement_ 1):i24–i31.

[20] Descours G, Desmurs L, Hoang TLT, et al. Evaluation of the Accelerate Pheno™ system for rapid identification and antimicrobial susceptibility testing of Gram-negative bacteria in bloodstream infections. *Eur J Clin Microbiol Infect Dis* 2018; 37: 1573–83.

[21] Giordano C, Piccoli E, Brucculeri V, et al. A Prospective Evaluation of Two Rapid Phenotypical Antimicrobial Susceptibility Technologies for the Diagnostic Stewardship of Sepsis. *Biomed Res Int* 2018; 2018: 6976923.

[22] Lutgring JD, Bittencourt C, McElvania TeKippe E, et al. Evaluation of the Accelerate Pheno™ System: Results from Two Academic Medical Centers. *J Clin Microbiol* 2018; 56.

specificity of 98.9 percent and AST CA of 94.1 percent. The applicant explained that the time to results for the Accelerate PhenoTest™ BC kit for use with the Accelerate Pheno™ system was 48.4 hours faster than standard of care (MicroScan WalkAway (ID and AST), MALDI or biochemical or API strips (ID)).

• The applicant explained that Marschal, et al.[23] is an equivalency performance paper showing ID sensitivity of 97.1 percent and AST CA of 96.4 percent. The applicant explained that the time to results for the Accelerate PhenoTest™ BC kit for use with the Accelerate Pheno™ system was 40.39 hours faster than standard of care (MALDI–TOF MS for ID and VITEK®2/Etest for AST).

• Pancholi, et al.[24] is an equivalency performance paper showing ID sensitivity of 97.5 percent and specificity of 99.5 percent and AST CA of 97.6 percent (GP) and 95.4 percent (GN) and AST EA of 97.9 percent (GP) and 94.3 percent GN. The applicant noted that standard of care was VITEK®2 for ID and BMD or DD for AST.

• Pantel, et al.[25] is an equivalency performance paper showing ID sensitivity of 100 percent and AST CA of 94.9 percent. The applicant explained that the standard of care was VITEK MS and VITEK®2 for ID and DD Etest for AST.

• Sofjan, et al.,[26] is an equivalency performance paper showing ID sensitivity of 98.0 percent and specificity of 99.5 percent and AST EA of 97.4 percent and CA of 97.9 percent. The applicant explained that the time to results for the Accelerate PhenoTest™ BC kit for use with the Accelerate Pheno™ system was 63.3 hours faster than standard of care (VITEK2 (ID and AST), Etest (AST)).

• Schneider, et al.[27] is an equivalency performance paper showing an AST CA of 94.7 percent. The applicant explained that the time to results for the Accelerate PhenoTest™ BC kit for use with the Accelerate Pheno™ system was 22.6 hours faster than standard of care (VITEK2 (AST)).

• Ward, et al.[28] is an equivalency performance paper showing ID sensitivity of 88.0 percent and AST EA of 91.6 percent and CA of 93.4 percent. According to the applicant, the time to results for the Accelerate PhenoTest™ BC kit for use with the Accelerate Pheno™ system was 41.95 hours faster than standard of care (MALDI–TOF MS for ID and VITEK2 + Verigene (BC–GP) for AST).

• Starr, et al.[29] is an equivalency performance paper showing AST EA of 96.5 percent and CA of 94.6 percent. The applicant explained that the average time to ID was reduced by 24.9 ± 6.9 hours and AST by 36.7 ±18.9 hours compared with standard of care (MALDI–TOF MS for ID and MicroScan and BMD for AST).

Additionally, the applicant provided four outcomes peer reviewed articles that it stated suggest the Accelerate PhenoTest™ BC kit for use with the Accelerate Pheno™ system improves clinical outcomes relative to services or technologies previously available as demonstrated by reducing clinically significant adverse events.

• Ehren, et al.[30] is a prospective outcome study that found statistically significant reduction for (1) time to step-down Abx therapy (p=0.019), (2) time to optimal antibiotic therapy (p=0.024), and (3) time to definitive therapy (p=0.005). The applicant noted that statistical significance was achieved despite low sample size of 204.

• Henig, et al., 2018 [31] is a retrospective outcome study reporting time to effective therapy (TTET) and time to definitive therapy (TTDT) of 25.9 h (Interquartile Range (IQR) 18.5, 42.1) and 47.6 h (IQR, 24.9, 79.6), respectively. The applicant explained that almost half of the patients had potential improvement in TTET and/or TTDT with Accelerate Pheno™ system. The applicant explained that in patients who would have had a benefit the median potential decreases in TTET and TTDT were 16.6 h (IQR, 5.5 to 30.6) and 29.8 h (IQR, 13.6 to 43), respectively.

• Henig, et al., 2019 [32] is a retrospective outcome study reporting a median time to effective therapy (TTET) of 2.4 h (IQR 0.5, 15.1), and Accelerate Pheno™ system results could have improved TTET in 4 patients (2.4%) by a median decrease of 18.9 h (IQR 11.3, 20.4). The applicant explained that the median time to definitive therapy (TTDT) was 41.4 h (IQR 21.7, 73.3) and Accelerate Pheno™ system results could have improved TTDT among 51 patients (30.5%), by a median decrease of 25.4 h (IQR 18.7, 37.5). The applicant explained that the Accelerate Pheno™ system implementation could have led to decreased usage of cefepime (16% less), aminoglycosides (23%), piperacillin-tazobactam (8%), and vancomycin (4%). The study noted that the impact of the Accelerate Pheno™ system on TTET was small, likely related to the availability of other rapid diagnostic tests at the study location.

• Schneider, et al.[33] paper had both an outcome and a performance component. The applicant explained that if Accelerate PhenoTest results had been available to inform patient care, 25 percent of patients could have been put on active therapy sooner, while 78 percent of patients who had therapy optimized during hospitalization could have had therapy optimized sooner. The applicant explained that additionally, Accelerate Pheno™ system results

[23] Marschal M, Bachmaier J, Autenrieth I, et al. Evaluation of the Accelerate Pheno System for Fast Identification and Antimicrobial Susceptibility Testing from Positive Blood Cultures in Bloodstream Infections Caused by Gram-Negative Pathogens. *J Clin Microbiol* 2017; 55: 2116–26.

[24] Pancholi P, Carroll KC, Buchan BW, et al. Multicenter Evaluation of the Accelerate PhenoTest™ BC Kit for Rapid Identification and Phenotypic Antimicrobial Susceptibility Testing Using Morphokinetic Cellular Analysis. *J Clin Microbiol* 2018; 56.

[25] Pantel A, Monier J, Lavigne JP. Performance of the Accelerate Pheno™ system for identification and antimicrobial susceptibility testing of a panel of multidrug-resistant Gram-negative bacilli directly from positive blood cultures. *J Antimicrob Chemother* 2018; 73: 1546–52.

[26] Sofjan AK, Casey BO, Xu BA, et al. Accelerate PhenoTest™ BC Kit Versus Conventional Methods for Identification and Antimicrobial Susceptibility Testing of Gram-Positive Bloodstream Isolates: Potential Implications for Antimicrobial Stewardship. *Ann Pharmacother* 2018; 52: 754–62.

[27] Schneider JG, Wood JB, Smith NW, et al. (2019) Direct antimicrobial susceptibility testing of positive blood cultures: A comparison of the accelerate Pheno™ and VITEK®2 systems. *Diagn Microbiol Infect Dis* [epub ahead of print].

[28] Ward E, Weller K, Gomez J, et al. Evaluation of a Rapid System for Antimicrobial Identification and Antimicrobial Susceptibility Testing in Pediatric Bloodstream Infections. *J Clin Microbiol* 2018. 56(9). pii: e00762–18.

[29] Starr KF, Robinson DC, and Hazen KC. Performance of the Accelerate Diagnostics Pheno™ system with resin-containing BacT/ALERT® Plus blood culture bottles. *Diagn Microbiol Infect Dis* 2019 pii: S0732–8893(18)30345–6.

[30] Ehren K, Meiβner A, Jazmati N, et al. Clinical impact of rapid species identification from positive blood cultures with same-day phenotypic antimicrobial susceptibility testing on the management and outcome of bloodstream infections. *Clin Infect Dis* 2019. ciz406 [Epub ahead of print].

[31] Henig O, Kaye KS, Chandramohan S, et al. The Hypothetical Impact of Accelerate Pheno™ (ACC) on Time to Effective Therapy and Time to Definitive Therapy for bloodstream infections due to drug-resistant Gram-negative bacilli. *Antimicrob Agents Chemother.* 2018. Epub ahead of print.

[32] Henig O, Cooper CC, Kaye KS, et al. The hypothetical impact of Accelerate Pheno on time to effective therapy and time to definitive therapy in an institution with an established antimicrobial stewardship program current utilizing rapid genotypic organism/resistance marker identification. *J Antimicrob Chemother* 2019. 74 (Supplement_1):i32–i39.

[33] Schneider JC, Wood JB, Bryan H, et al. Susceptibility Provision Enhances Effective De-Escalation (SPEED). Utilizing Rapid Phenotypic Susceptibility Testing in Gram-Negative Bloodstream Infections and its Potential Clinical Impact. *J Antimicrob Chemother* 2019. 74 (Supplement_1):i16-i23.

could have reduced time to de-escalation (16 versus 31 h) and escalation (19 versus 31 h) compared with SOC. The applicant further explained that the paper reported an ID sensitivity of 95.9 percent, specificity of 99.9 percent, AST EA of 94.5 percent, and CA of 93.5 percent. The applicant explained that the time to results for the Accelerate PhenoTest™ BC kit for use with the Accelerate Pheno™ system was 26 hours faster than SOC (Verigene BCID–GN and MALDI–TOF MS for ID, and VITEK2 and BMD for AST).

Additionally, the applicant provided six posters that were presented at conferences to support its claims of substantial clinical improvement.

• Dare, et al.[34] poster provided an interim analysis of a dataset (N=154) from single center, retrospective chart review study that showed 3-day reduction in length of stay (LOS) (p=0.03), 2-day reduction in days on therapy (DOT) (p=0.05), and 36-hour reduction in time to optimal therapy (TTOT) (p<0.001).

• Sheth, et al.[35] poster provided an interim analysis of a dataset (N=173) from a quasi-experimental outcome study (with a prospective and retrospective arm). The applicant explained that it showed a 2-day reduction in length of stay (LOS) (p=0.002), reduction in antibiotic intensity score (p=0.0002), and reduction of median days broad-spectrum antibiotics (p<0.0001).

• Chirca, et al.[36] poster provided a prospective analysis of positive blood cultures. The applicant explained that it showed that after the implementation of the Accelerate Pheno™ system, there was a decrease in sepsis due to bloodstream infections (BSI) as a percentage of inpatient mortality and average number of antibiotic days.

• Banerjee, et al.[37] was a prospective randomized study of 448 patients. The applicant explained that it showed a significant reduction in the time to results (AST: 13 vs. 54.6 h, p<0.001), time to first antibiotic modification (8.6 vs. 14.9 h, p=0.02) and time to gram negative antibiotic modification (17.4 vs. 42.1 h, p<0.0001).

• Pearson, et al.,[38] provided a quasi-experimental before/after study of 496 patients. The applicant explained that it showed significant reduction in length of stay (LOS) (9.54 vs 11.89 days, p<0.01). reduction in time to optimal therapy days (TTOT) (1.58 v 2.69, p<0.01), and reduction in time to optimal treatment (95.4% vs 84.6%, p<0.01).

• Kinn, et al.[39] showed that recommendations (bug-drug mismatch, de-escalation, dose optimization, and infectious disease consult) were accepted at a rate of 97.4 percent, according to the applicant.

The applicant also explained that an oral presentation by Walsh, et al.[40] detailed the clinical improvements an institution realized since implementing the Accelerate PhenoTest™ BC kit, including a 4.6 day reduction in days of antimicrobial therapy, a 2.2 day reduction in ICU length of stay, and a decrease in sepsis-related readmission rates from 21.8 percent to 14.3 percent.

The applicant asserted that these studies supported that the technology represents a substantial clinical improvement, for the following reasons:

• The claim of reduction in time to AST results is supported by evidence, per the applicant, from 10 out of 19 studies that show the time to AST results over standard of care (SOC) are 40.1, 40.8, 41.86, 24.4, 48.4, 40.39, 63.3, 22.6, 41.96, and 36.7 hours, which averages to 40.05 hours. The applicant asserted that this reduction shows the ability to diagnose a medical condition (antibiotic resistance or susceptibility) earlier than allowed by currently available methods. The applicant cited the following studies to support this claim: Brazelton,[41] Burnham,[42] Charnot-Katsikas,[43] Descours,[44] Lutgring,[45] Marschal,[46] Sofjan,[47] Schneider,[48] Ward,[49] and Starr.[50]

• The claim of reduction in hands-on time is supported, according to the applicant, by evidence from the Charnot-Katsikas [51] study, which the applicant stated shows a reduction in hands on time observed of 25.5 min per culture over standard of care methods.

• The applicant stated that the Ehren [52] study supports four of its

[34] Dare, R., McCain, K., Lusardi, K., et al. Impact of Accelerate Pheno™ Rapid Blood Culture Detection System on Laboratory and Clinical Outcomes in Bacteremic Patients. Poster presented at: ID Week; October 2018, San Francisco, CA. *https://idsa.confex.com/idsa/2018/webprogram/Paper70067.html.*

[35] Sheth S, Miller M, Baker S. Impact of rapid identification and antimicrobial susceptibility testing on antibiotic therapy and outcomes for patients with Gram-negative bacteraemia or candidaemia at an acute care hospital. Poster presented at: The 2019 European Congress of Clinical Microbiology and Infectious Disease (ECCMID); Amsterdam.

[36] Chirca I, Albrecht A, Patel A, et al. Integration of a new rapid diagnostic test with antimicrobial stewardship in a community hospital. Poster presented at: The Society for Healthcare Epidemiology of America 2019 Boston, MA.

[37] Banerjee R, Komarow L, Virk A, et al. Randomized Clinical Trial Evaluating Clinical Impact of RAPid IDentification and Antimicrobial Susceptibility Testing for Gram-Negative Bacteremia (RAPIDS–GN). Poster presented at: ID Week; October 2019, Washington, DC.

[38] Pearson C, Lusardi K, McCain K, et al. Impact of Accelerate Pheno™ Rapid Blood Culture Detection System with Real Time Notification versus Standard Antibiotic Stewardship on Clinical Outcomes in Bacteremic Patients. Abstract and Poster presented at: ID Week; October 2019, Washington, DC.

[39] Kinn et al. Real-World Impact of Accelerate Pheno Implementation with Antimicrobial Stewardship Intervention. Poster presented at IDWeek™ 2019.

[40] Walsh, Thomas. Impact of Accelerate Pheno™ System on Management of Gram Negative Bacteremia at an Academic Medical Center. Oral presentation given at SCACM West Virginia 2019.

[41] Brazelton de Cardenas JN, Su Y, Rodriguez A, et al. Evaluation of rapid phenotypic identification and antimicrobial susceptibility testing in a pediatric oncology center. *Diagn Microbiol Infect Dis* 2017; 89: 52–7.

[42] Burnham JP, Wallace MA, Fuller BM, et al. Clinical Effect of Expedited Pathogen Identification and Susceptibility Testing for Gram-Negative Bacteremia and Candidemia by Use of the Accelerate Pheno™ System. *J Appl Lab Med* 2019. 3(6):569.

[43] Charnot-Katsikas A, Tesic V, Love N, et al. Use of the Accelerate Pheno™ System for Identification and Antimicrobial Susceptibility Testing of Pathogens in Positive Blood Cultures and Impact on Time to Results and Workflow. *J Clin Microbiol* 2018; 56.

[44] Descours G, Desmurs L, Hoang TLT, et al. Evaluation of the Accelerate Pheno™ system for rapid identification and antimicrobial susceptibility testing of Gram-negative bacteria in bloodstream infections. *Eur J Clin Microbiol Infect Dis* 2018; 37: 1573–83.

[45] Lutgring JD, Bittencourt C, McElvania TeKippe E, et al. Evaluation of the Accelerate Pheno™ System: Results from Two Academic Medical Centers. *J Clin Microbiol* 2018; 56.

[46] Marschal M, Bachmaier J, Autenrieth I, et al. Evaluation of the Accelerate Pheno System for Fast Identification and Antimicrobial Susceptibility Testing from Positive Blood Cultures in Bloodstream Infections Caused by Gram-Negative Pathogens. *J Clin Microbiol* 2017; 55: 2116–26.

[47] Sofjan AK, Casey BO, Xu BA, et al. Accelerate PhenoTest™ BC Kit Versus Conventional Methods for Identification and Antimicrobial Susceptibility Testing of Gram-Positive Bloodstream Isolates: Potential Implications for Antimicrobial Stewardship. *Ann Pharmacother* 2018; 52: 754–62.

[48] Schneider JG, Wood JB, Smith NW, et al. (2019) Direct antimicrobial susceptibility testing of positive blood cultures: A comparison of the accelerate Pheno™ and VITEK® 2 systems. *Diagn Microbiol Infect Dis* [epub ahead of print].

[49] Ward E, Weller K, Gomez J, et al. Evaluation of a Rapid System for Antimicrobial Identification and Antimicrobial Susceptibility Testing in Pediatric Bloodstream Infections. *J Clin Microbiol* 2018. 56(9). pii: e00762–18.

[50] Starr KF, Robinson DC, and Hazen KC. Performance of the Accelerate Diagnostics Pheno™ system with resin-containing BacT/ALERT® Plus blood culture bottles. *Diagn Microbiol Infect Dis* 2019 pii: S0732–8893(18)30345–6.

[51] Charnot-Katsikas A, Tesic V, Love N, et al. Use of the Accelerate Pheno™ System for Identification and Antimicrobial Susceptibility Testing of Pathogens in Positive Blood Cultures and Impact on Time to Results and Workflow. *J Clin Microbiol* 2018; 56.

[52] Ehren K, Meißner A, Jazmati N, et al. Clinical impact of rapid species identification from positive blood cultures with same-day phenotypic antimicrobial susceptibility testing on the management and outcome of bloodstream infections. Clin Infect Dis 2019. Ciz406 [Epub ahead of print].

claims regarding substantial clinical improvement.

++ Per the applicant, the claim of decreased time to step-down therapy is supported by the findings in that study that the time to step-down antimicrobial therapy was significantly decreased in the Accelerate Pheno™ BC kit with antimicrobial stewardship intervention (12 h; p= 0.019).

++ Per the applicant, the claim of decreased time to initiation of definitive therapy (TTDT) is supported by the findings that the time to recommendation of definitive therapy (26.5 vs. 7.7 h, p=0.000) and time to definitive therapy (TTDT) (25.7 vs. 7.5 h, p=0.005) was significantly shorter using the Accelerate Pheno™ BC kit with antimicrobial stewardship intervention.

++ Per the applicant, the claim of decreased time to optimal therapy (TTOT) is supported by the findings that the use of Accelerate Pheno™ BC kit significantly decreased time from Gram stain to ID (23 vs. 2.2 h, p<0.001) and AST (23 vs. 7.4 hours, p<0.001) and decreased time from Gram stain to optimal therapy (11 vs. 7 hours, p=0.024) and to step-down antimicrobial therapy (27.8 vs. 12 hours, p=0.019).

++ Per the applicant, the claim of decreased use of aminopenicillin + ß-lactamase is supported by the findings that within 5 days after blood culture draw, utilization of aminopenicillins + ß-lactamase inhibitors was significantly reduced (26.4 vs. 9.7 h, p<0.001) in the group with Accelerate Pheno™ BC kit with antimicrobial stewardship.

• The applicant stated that the first Henig [53] study supports two of its claims regarding substantial clinical improvement.

++ Per the applicant, the claim of time to effective therapy (TTET) is supported by the findings that the TTET was 25.9 h, and almost half of the patients had potential improvement in TTET and/or TTDT with Accelerate Pheno™ BC kit. The applicant explained that in patients who would have had a benefit, the median potential decrease in TTET was 16.6 h.

++ Per the applicant, the claim of time to definitive therapy (TTDT) is supported by the findings that the TTDT was 47.6 h, and almost half of the patients had potential improvement in TTET and/or TTDT with Accelerate Pheno™ BC kit. The applicant explained that in patients who would have had a benefit, the median potential decrease in TTDT was 29.8 h.

• The applicant stated that the second Henig [54] study supports three of its claims regarding substantial clinical improvement.

++ Per the applicant, the claim of time to effective therapy (TTET) is supported by the conclusion that had the Accelerate Pheno™ BC kit results been available, TTET could have been improved in 2.4 percent of patients by a median decrease of 18.9 h, with 75 percent of these patients having blood stream infections with ESBL-producing *Enterobaceriaceae.*

++ Per the applicant, the claim of decreased use of cefepime, aminoglycosides, piperacillin-tazobactam, and vancomycin is supported by the findings that with the Accelerate Pheno™ BC kit, results show there was a decreased usage of cefepime (16% less), aminoglycosides (23%), piperacillin-tazobactam (8%) and vancomycin (4%).

++ Per the applicant, the claim of time to definitive therapy (TTDT) is supported by the findings that nearly one-third of patients, 30.5 percent, could have received definitive therapy more rapidly had Accelerate Pheno™ BC kit results been available in real time. Additionally, the applicant explained that a potential benefit in TTDT was demonstrated in 53 percent of patients with CRE, 61.5 percent of patients with ESBL,[55] and 20 percent of patients with non-fermenting bacteria. The applicant explained that the potential median decrease in TTDT among those who could have had a benefit if Accelerate Pheno™ BC kit results had been available was 25.4 h (IQR, 18.7, 37.5).

• The applicant stated that the Schneider [56] study supports two of its claims regarding substantial clinical improvement.

++ Per the applicant, the claim of decreased time to active therapy and time to optimal therapy (TTOT) is supported by the findings that if Accelerate PhenoTest results had been available to inform patient care 25 percent of patients could have been put on active therapy sooner, and 78 percent of patients who had therapy optimized could have had therapy optimized sooner.

++ Per the applicant, the claim of ''reduce time to de-escalation or escalation'' is supported by the findings that the Accelerate PhenoTest could have reduced the time to de-escalation (16 versus 31 h) and escalation (19 versus 31 h) compared with standard of care (SOC).

• The applicant stated that the Dare [57] study supports three of its claims regarding substantial clinical improvement.

++ Per the applicant, the claim of decreased time to active therapy and time to optimal therapy (TTOT) is supported by the findings of a decrease in length of stay from a mean of 12.1 days under the standard of care to 9.1 days under the Accelerate PhenoTest system.

++ Per the applicant, the claim of time to optimal therapy (TTOT) is supported by the findings of a reduction from 73.5 hours under the standard of care to 37.5 hours under the Accelerate PhenoTest system.

++ Per the applicant, the claim of total antibiotic days on therapy (DOT) is supported by the findings of a reduction from 9 days under the standard of care to 7 days under the Accelerate PhenoTest system.

• The applicant stated that the Sheth [58] study supports three of its claims regarding substantial clinical improvement.

++ Per the applicant, the claim of reduced length of stay (LOS) is supported by the findings of a reduction in length of stay from 8 days with VERIGENE to 6 days with the Accelerate PhenoTest system.

++ Per the applicant, the claim of reduction in antibiotic intensity score is supported by the findings of a reduction from 16 with VERIGENE to 12 with the Accelerate PhenoTest system.

++ Per the applicant, the claim of reduction of median days broad-

[53] Henig O, Kaye KS, Chandramohan S, et al. The Hypothetical Impact of Accelerate Pheno™ (ACC) on Time to Effective Therapy and Time to Definitive Therapy for bloodstream infections due to drug-resistant Gram-negative bacilli. *Antimicrob Agents Chemother.* 2018. Epub ahead of print.

[54] Henig O, Cooper CC, Kaye KS, et al. The hypothetical impact of Accelerate Pheno™ on time to effective therapy and time to definitive therapy in an institution with an established antimicrobial stewardship program current utilizing rapid genotypic organism/resistance marker identification. *J Antimicrob Chemother* 2019. 74 (Supplement_1):i32-i39.

[55] CRE = Carbapenem-resistant Enterobacteriaceae, ESBL = Extended Spectrum Beta-Lactamases.

[56] Schneider JC, Wood JB, Bryan H, et al. Susceptibility Provision Enhances Effective De-Escalation (SPEED). Utilizing Rapid Phenotypic Susceptibility Testing in Gram-Negative Bloodstream Infections and its Potential Clinical Impact. J Antimicrob Chemother 2019. 74 (Supplement_1):i16–i23.

[57] Dare, R., McCain, K., Lusardi, K., et al. Impact of Accelerate Pheno™ Rapid Blood Culture Detection System on Laboratory and Clinical Outcomes in Bacteremic Patients. Poster presented at: ID Week; October 2018, San Francisco, CA.

[58] Sheth S, Miller M, Baker S. Impact of rapid identification and antimicrobial susceptibility testing on antibiotic therapy and outcomes for patients with Gram-negative bacteraemia or candidaemia at an acute care hospital. Poster presented at: *The 2019 European Congress of Clinical Microbiology and Infectious Disease (ECCMID);* Amsterdam.

spectrum antibiotics is supported by the findings of a reduction of median days on broad-spectrum antibiotics from 2 days with VERIGENE to 1 day with the Accelerate PhenoTest system.

• The applicant stated that the Chirca [59] study supports two of its claims regarding substantial clinical improvement.

++ Per the applicant, the claim of reduction of inpatient mortality is supported by the findings of a decrease in sepsis due to BSIs [60] (as a percentage of inpatient mortality) from 10.9 percent to 7 percent for the duration of the study, with a consistent downward slope. The applicant noted a statistically significant decrease in inpatient mortality in cases of proven BSI; the rate of decrease is estimated at 0.27 percent per month with a 95 percent confidence interval of (0.12%–0.41%) per month, p = 0.001.

++ Per the applicant, the claim of reduction in average number of antibiotic days is supported by the finding that the average number of antibiotic days per patient encounter was reduced by 1 full day, from 6.8 to 5.8 days.

• The applicant stated that the Banerjee [61] study supports three of its claims regarding substantial clinical improvement.

++ Per the applicant, the claim of time to results is supported by the findings that the Accelerate Pheno™ system provided identification (ID) results (2.7 vs. 15.6 h, p<0.001) and antimicrobial susceptibility test (AST) results (13 vs. 54.6 h, p<0.001) faster than standard of care (SOC).

++ Per the applicant, the claim of time to first antibiotic modification is supported by the finding that the average time to first antibiotic modification was reduced from 14.9 hours to 8.6 hours.

++ Per the applicant, the claim of time to first gram negative antibiotic modification is supported by the finding that the time to first gram negative antibiotic modification was reduced from 42.1 hours to 17.4 hours. The applicant also explained that time to antimicrobial therapy change was reduced by 24.8 hours for patients with Gram-negative bacteremia.

• The applicant stated that the Pearson [62] study supports three of its claims regarding substantial clinical improvement.

++ Per the applicant, the claim of reduction in length of stay (LOS) is supported by the findings that the Accelerate Pheno™ system showed a significant reduction in length of stay (9.54 vs 11.89 days, p<0.01).

++ Per the applicant, the claim of time to optimal therapy (TTOT) is supported by the finding that the Accelerate Pheno™ system showed a significant reduction in time to optimal therapy days (TTOT) (1.58 v 2.69, p<0.01).

++ Per the applicant, the claim of time to optimal treatment achieved is supported by the finding that the Accelerate Pheno™ system showed a significant reduction in time to optimal treatment (95.4% vs 84.6%, p<0.01). The applicant also noted that time to optimal antimicrobial therapy was reduced by 19.2 hours, overall days of antimicrobial therapy were reduced by 1.6 days, and length of stay was reduced by 2.4 days.

The applicant stated that its claim of acceptance of therapeutic recommendations is supported by the Kinn [63] study, which the applicant stated found that recommendations of bug-drug mismatch, de-escalation, dose optimization, and infectious disease consultation were accepted at a rate of 97.4 percent. The applicant also noted that time to optimal antimicrobial therapy was reduced by 15.3 hours for bacteremic patients.

After reviewing the information submitted by the applicant as part of its FY 2021 new technology add-on payment application, we are concerned that the studies the applicant provided are either unclear about which version of the Accelerate PhenoTest™ BC kit was used or indicate that the first version of the device was used in the study. The applicant appears to rely mainly on studies conducted on the first version of the device, which has been on the market since February 2017, as compared to other products to establish substantial clinical improvement, although it was not always clear in each study which version was being used. The applicant submitted its application for new technology add-on payments for the updated version of the Accelerate PhenoTest™ BC kit submitted to FDA for 510(k) clearance in 2019. However, the applicant did not present any clinical data to distinguish the clinical outcomes achieved by the updated version as compared to the original version. We would be interested in additional information on which studies involved the first version of the device, which has been commercially available since February 2017, and which studies involved the updated version of the device for which the applicant submitted its new technology add-on payment application. We note that several of the studies submitted by the applicant in support of substantial clinical improvement showed empirical results that were less favorable to the Accelerate PhenoTest™ BC kit as compared to the current standard of care. For instance, an analysis of discrepant results in Decours et al. found impaired performance of the Accelerate Pheno™ system for beta-lactams (except cefepime) in *Enterobacteriales* (six very major errors) and poor performance in *P. aeruginosa.*[64] In addition, Giordano et al. did not show superiority for the Accelerate PhenoTest™ BC kit against SOC comparisons (MALDI–TOF for ID and Sensitive/traditional BMD for AST), on any of several measures including sensitivity and time to get results back from the testing.[65]

We invite public comments on whether the updated version of the Accelerate PhenoTest™ BC kit meets the substantial clinical improvement criterion.

In this section, we summarize and respond to written comments we received in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for the Accelerate PhenoTest™ BC kit.

Comment: In response to a question presented at the New Technology Town Hall meeting, the applicant provided a table with study details on the clinical outcomes studies they presented, which are also referenced and summarized in part previously, as well as for study data comparing clinical outcomes resulting

[59] Chirca I, Albrecht A, Patel A, et al. Integration of a new rapid diagnostic test with antimicrobial stewardship in a community hospital. Poster presented at: *The Society for Healthcare Epidemiology of America 2019* Boston, MA.

[60] BSI = bloodstream infections.

[61] Banerjee R, Komarow L, Virk A, et al. Randomized Clinical Trial Evaluating Clinical Impact of RAPid IDentification and Antimicrobial Susceptibility Testing for Gram-Negative Bacteremia (RAPIDS–GN). *Poster presented at: ID Week; October 2019,* Washington, DC.

[62] *Pearson C, Lusardi K, McCain K, et al. Impact of Accelerate Pheno™ Rapid Blood Culture Detection System with Real Time Notification versus Standard Antibiotic Stewardship on Clinical Outcomes in Bacteremic Patients. Poster presented at: ID Week; October 2019, Washington, DC.*

[63] *Kinn P, Percival K, Ford B, et al. Real-World Impact of Accelerate Pheno™ system Implementation with Antimicrobial Stewardship Intervention. Poster presented at: ID Week; October 2019, Washington, DC.*

[64] Descours G, Desmurs L, Hoang TLT, et al. Evaluation of the Accelerate Pheno™ system for rapid identification and antimicrobial susceptibility testing of Gram-negative bacteria in bloodstream infections. *Eur J Clin Microbiol Infect Dis* 2018; 37: 1573–83.

[65] Giordano C, Piccoli E, Brucculeri V, et al. A Prospective Evaluation of Two Rapid Phenotypical Antimicrobial Susceptibility Technologies for the Diagnostic Stewardship of Sepsis. *Biomed Res Int* 2018; 2018: 6976923.

from use of the Accelerate PhenoTest® BC kit to use of standard of care methodologies for determining antibiotic susceptibility testing. Regarding Banerjee R., et al., the applicant explained that the study was conducted at Mayo Clinic and University of California, Los Angeles; the study type was a multicenter, prospective randomized controlled trial with a sample of 448 (226 SOC, 222 AXDX); SOC testing included rapid MALDI–TOF mass spectrometry ID and agar dilution or broth microdilution AST; and the conclusions were median (interquartile range) hours to first Gram-negative antibiotic modification (including escalation and de-escalation) 24.7 hours faster in the AXDX than SOC group 17.4 (4.9, 72) vs. 42.1 (10.1, 72), $p<0.001$.[66] Regarding Pearson C., et al., the applicant explained that the study was conducted by University of Arkansas for Medical Science; the study type was a single center, quasi-experimental study of bacteremic adult inpatients before and after implementation of AXDX; the N was 496 (188 historical, 155 Intervention 1, 153 Intervention 2); SOC was historical ID/AST performed using VITEK® MS and VITEK®2; and conclusions were reduced inpatient length of stay (LOS) by 2.4 days, reduced days on therapy (DOT) by 1.6 days, reduced broad-spectrum Gram-positive antibiotic therapy by 0.7 days, and reduced broad-spectrum Gram-negative antibiotic therapy by 1.7 days.[67] Regarding Kinn P., et al., the applicant explained that the study was conducted at the University of Iowa; the study type was observational, which included an interrupted time series sub-study; the N was 690 (417 in A; 273 in B); SCO as MALDI for organism identification and VITEK®2 and/or Sensititre™ for AST; and conclusions were implementation of AXDX with AST review resulted in fast identification and antibiotic susceptibility results with early optimization of antimicrobial therapy.[68] Regarding Walsh T., the applicant explained that the study was conducted at Allegheny General Hospital (AGH); it was a quasi-experimental study of bacteremic patients before and after implementation of AXDX with positive blood cultures tested at AGH from both AGH and West Penn Hospital; the N was 208 (of non-ICU patients, 78 in the pre-AXDX arm and 63 in the post-AXDX arm, and of ICU patients: 36 in the pre-AXDX arm and 31 in the post-Accelerate arm); VITEK®2 was used for both ID and AST results in the control arm; and conclusions were DOT reduced by 4.6 days, 2.2 day reduction in ICU LOS, and readmission rate reduced from 21.8 percent to 14.3 percent.[69] Regarding Sheth S., et al., the applicant explained that the study was conducted at Peninsula Regional Medical Center; the study consisted of a retrospective (pre-implementation group with VERIGENE® system testing for 100 patients) arm and a prospective (postimplementation of fast ID/AST with AXDX for 100 patients) group; the N was 173 (84 in the pre-implementation arm and 89 in the AXDX arm); SOC was the VERIGENE® system; and conclusions were reduced inpatient LOS by 2.0 days, reduced broad-spectrum days on therapy by 2.0 days.[70]

Response: We appreciate the applicant's further explanation of these study details and data. We will take this information into consideration when deciding whether to approve new technology add-on payments for the Accelerate PhenoTest® BC kit.

Comment: In response to a question presented at the New Technology Town Hall meeting, the applicant explained that T2 Biosystems' instrument is designed for whole blood samples. The applicant stated that T2 Biosystems has two FDA-cleared assays, a *Candida* panel with five target organisms and a Bacteria panel with five target organisms. The applicant stated that the assay turnaround times for T2 Biosystems vary from 3 hours to 5 hours. The applicant further stated that neither of the T2 Biosystems FDA-cleared products provide antibiotic susceptibility testing results; in other words, they perform identification only, but do not yield antimicrobial susceptibility/resistance results. The applicant explained that, in contrast, the Accelerate PhenoTest® BC kit contains 116 assays, providing organism identification results (16 assays: 8 Gram-negative bacterial targets, 6 Gram-positive bacterial targets and 2 Candida spp.) as well as antibiotic susceptibility testing (100 assays) information for approximately 91 percent of positive blood cultures and that it has a turnaround time of approximately 7 hours after blood culture positivity. The applicant also stated that antimicrobial susceptibility testing with the Accelerate PhenoTest® BC kit is included for Gram-positive organisms: Ampicillin, Ceftaroline, Erythromycin, Daptomycin, Linezolid, Vancomycin, Methicillin resistance (cefoxitin), MLSb (Erythromycin-clindamycin); and for Gram-negative organisms: Ampicillin-sulbactam, Piperacillin-tazobactam, Cefepime, Ceftazidime, Ceftriaxone, Ertapenem, Meropenem, Amikacin, Gentamicin, Tobramycin, Ciprofloxacin, Aztreonam.

Response: We appreciate the applicant's explanation of the Accelerate PhenoTest® BC kit and how the technology differs from T2 Biosystems' instrument. We will take this information into consideration when deciding whether to approve new technology add-on payments for the Accelerate PhenoTest® BC kit.

b. BioFire® FilmArray® Pneumonia Panel

BioFire Diagnostics, LLC submitted an application for new technology add-on payments for the BioFire® FilmArray® Pneumonia Panel for FY 2021. According to the applicant, the BioFire® FilmArray® Pneumonia Panel identifies 33 clinically relevant targets, including bacterial and viral targets, from sputum (including endotracheal aspirate) and bronchoalveolar lavage (including mini-BAL) samples in about an hour. The applicant also stated that for 15 bacteria, the BioFire® FilmArray® Pneumonia Panel provides semi-quantitative results, which may help determine whether an organism is a colonizer or a pathogen.

According to the applicant, lower respiratory tract infections are a leading cause of morbidity and mortality. The applicant stated that world-wide, they are the leading cause of infectious disease death and the 5th leading overall cause of death.[71] The applicant

[66] Banerjee R, Komarow L, Virk A, et al. Randomized Clinical Trial Evaluating Clinical Impact of RAPid IDentification and Antimicrobial Susceptibility Testing for Gram-Negative Bacteremia (RAPIDS–GN). Poster presented at: ID Week; October 2019, Washington, DC.

[67] Pearson C, Lusardi K, McCain K, et al. Impact of Accelerate Pheno™ Rapid Blood Culture Detection System with Real Time Notification versus Standard Antibiotic Stewardship on Clinical Outcomes in Bacteremic Patients. Presented at: ID Week; October 2019, Washington, DC.

[68] Kinn et al., Real-World Impact of Accelerate Pheno Implementation with Antimicrobial Stewardship Intervention. Poster presented at IDWeek™ 2019.

[69] Walsh, Thomas. Impact of Accelerate Pheno™ System on Management of Gram Negative Bacteremia at an Academic Medical Center. Oral presentation given at SCACM West Virginia 2019.

[70] Sheth S, Miller M, Baker S. Impact of rapid identification and antimicrobial susceptibility testing on antibiotic therapy and outcomes for patients with Gram-negative bacteraemia or candidaemia at an acute care hospital. Presented at: The 2019 European Congress of Clinical Microbiology and Infectious Disease (ECCMID); Amsterdam.

[71] Troeger, C., Forouzanfar, M., Rao, P.C., Khalil, I., Brown, A., Swartz, S., Fullman, N., Mosser, J., Thompson, R.L., Reiner Jr, R.C. and Abajobir, A., ''Estimates of the global, regional, and national morbidity, mortality, and aetiologies of lower respiratory tract infections in 195 countries: a

Continued

also asserted that in the United States, community acquired pneumonia (CAP) is the second most common cause of hospitalization and the most common infectious disease cause of death.[72] [73] The applicant also stated that in addition to CAP, Hospital-acquired Pneumonia (HAP) and Ventilator-associated Pneumonia (VAP) are the most common hospital acquired infections (HAI) accounting for 22 percent of all HAIs.[74] According to the applicant, HAP and VAP are of particular concern for patients admitted to intensive care units (ICUs) where mortality rates can be up to 50 percent.[75] [76]

According to the applicant, timely administration of effective antibiotics is essential for ensuring a good prognosis. The applicant stated that mortality increases for each hour of delay in initiating antibiotic therapy for hospitalized pneumonia patients,[77] [78] and ideally, antimicrobial therapy would be pathogen specific and guided by the results of microbiology tests. However, the applicant stated that current microbiologic methods are slow and fail to identify a causative pathogen in over 50 percent of patients, even when comprehensive methods are used.[79] As a result, the applicant noted that current guidelines recommend empiric treatment with broad spectrum antibiotics,[80] and that broad-spectrum antibiotics lead to overuse of antibiotics, which increases the risk of an antibiotic related adverse event (for example, diarrhea, allergic reactions, C. difficile infection) for the patient and contributes to the well-known problem of antimicrobial resistance. In addition, the applicant noted that 6–15 percent of hospitalized patients with CAP fail to respond to the initial antibiotic treatment, in part due to ineffective antibiotic therapy.[81] [82] [83] [84]

According to the applicant, there are three current methods for determining the causative organism of pneumonia: bacterial culture, lab developed and commercial singleplex PCR (Polymerase Chain Reaction) tests, and off-label use of upper respiratory multiplex syndromic panels.

According to the applicant, semi-quantitative bacterial culture is routinely performed on lower respiratory specimens. The applicant explained that a calibrated loop is used to spread sample on appropriate media. A quadrant streak method is generally employed and, depending on how many of the quadrants the organism grows in, determines its semi-quantification. According to the applicant, normal flora will often grow in all 4 quadrants and technicians must differentiate between potential pathogens and normal flora, and potential pathogens are picked from the plate and isolated on another media plate. According to the applicant, after growing isolate, final identification and susceptibility is performed.

According to the applicant, there are also FDA and lab developed tests for single targets that cause pneumonia. The applicant stated that that these are for the more serious pathogens (for example. Methicillin resistant *Staphylococcus aureus,* MRSA) or fastidious organisms (for example *Mycobacterium tuberculosis*). According to the applicant, these tests range from sample-to-answer (Cepheid® Xpert® MTB/RIF) to lab developed tests that are often multi-step and multiple pieces of equipment that require isolating nucleic acid from a sample and then adding appropriate reagents to perform a PCR assay on the isolated nucleic acid.

According to the applicant, a number of academic hospital labs have also performed off label validation of commercially available respiratory panels designed for upper respiratory syndromes. The applicant stated that these tests are used primarily on BAL specimens for the rapid detection of viral causes of Pneumonia.

With respect to the newness criterion, the BioFire® FilmArray® Pneumonia Panel received FDA clearance via 510(k) on November 9, 2018, based on a determination of substantial equivalence to a legally marketed predicate device (Curetis Unyvero™). According to the applicant, the Pneumonia Panel was launched globally on December 11, 2018. According to the applicant, there was a delay between FDA clearance date and U.S. market availability (global launch date) in order to satisfy documentation requirements in preparation of the global launch. The applicant stated that it has been granted a Proprietary Laboratory Analyses (PLA) code by the American Medical Association; PLA Code 0151U was published on October 1st, 2019 and became effective on January 1st, 2020. According to the applicant, the PLA code assigned to the BioFire® FilmArray® Pneumonia Panel uniquely identifies this test and no other technologies use this code. Currently, there are no ICD–10–PCS procedure codes to uniquely identify procedures involving the BioFire® FilmArray® Pneumonia Panel. We note that the applicant has submitted a request for approval for a unique ICD–10–PCS code for the administration of the BioFire® FilmArray® Pneumonia Panel beginning in FY 2021.

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be

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[80] Kalil, A.C., Metersky, M.L., Klompas, M., Muscedere, J., Sweeney, D.A., Palmer, L.B., Napolitano, L.M., O'Grady, N.P., Bartlett, J.G., Carratalà, J. and El Solh, A.A., ''Management of adults with hospital-acquired and ventilator-associated pneumonia: 2016 clinical practice guidelines by the Infectious Diseases Society of America and the American Thoracic Society,'' *Clin. Infect. Dis.,* 2016, vol. 63(5), pp.e61-e111.

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[82] Menendez, R., Torres, A., Zalacain, R., Aspa, J., Villasclaras, J.M., Borderías, L., Moya, J.B., Ruiz-Manzano, J., de Castro, FR, Blanquer, J. and Pérez, D., ''Risk factors of treatment failure in community acquired pneumonia: implications for disease outcome,'' *Thorax,* 2004. Vol. 59(11), pp. 960–965.

[83] Arancibia, F., Ewig, S., Martinez, J.A., Ruiz, M., Bauer, T., Marcos, M.A., Mensa, J. and Torres, A., ''Antimicrobial treatment failures in patients with community-acquired pneumonia: causes and prognostic implications,'' *Am. J. Respir. Crit. Care Med.,* 2000, vol. 162(1), pp.154–160.

[84] Menéndez, R., Torres, A., Rodríguez de Castro, F., Zalacaín, R., Aspa, J., Martín Villasclaras, J.J., Borderías, L., Benítez, J.M.M., Ruiz-Manzano, J., Blanquer, J. and Pérez, D., ''Reaching stability in community-acquired pneumonia: the effects of the severity of disease, treatment, and the characteristics of patients,'' *Clin. Infect. Dis.,* 2004, vol. 39(12), pp.1783–1790.

considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, according to the applicant, the BioFire® FilmArray® Pneumonia Panel is the only sample-to-answer, rapid (~1 hour), and comprehensive molecular panel available for the diagnosis of the major causes of infectious pneumonia. The applicant further explained that the BioFire® FilmArray® Pneumonia Panel is also the only semi-quantitative molecular solution available for rapidly diagnosing infectious causes of pneumonia. The applicant noted that this important feature allows labs and clinicians to better differentiate whether an organism is normal flora or the cause of the patient's illness. The applicant asserted that the current best practice is standard culture technique, discussed previously. The applicant further stated that other comprehensive molecular technologies include Curetis Unyvero™ which is a multi-step process, only has bacterial targets, and only provides qualitative results for all of its targets.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that potential cases representing patients who may be eligible for treatment involving the BioFire® FilmArray® Pneumonia Panel would be assigned to the same MS–DRGs as cases representing patients who receive diagnostic information from competing technologies.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, according to the applicant, the BioFire® FilmArray® Pneumonia Panel is the only FDA cleared comprehensive molecular panel approved for use on both sputum (including endotracheal aspirate) and bronchoalveolar lavage (including mini-BAL) samples allowing for diagnosis of pneumonia in hospital, community, and ventilator associated populations. The applicant stated that the BioFire® FilmArray® Pneumonia Panel is also the only molecular panel that detects both bacterial and viral causes of lower respiratory infections and pneumonia.

In addition, the applicant added that the ability of the BioFire® FilmArray® Pneumonia Panel to detect pathogens and related susceptibility traits is a unique feature of the panel that differentiates it from existing respiratory panels that have been designed and approved for use on upper respiratory specimens and not lower respiratory specimens. The applicant stated that Furukawa, D., et al., evaluated the ability of the BioFire® FilmArray® Pneumonia Panel to detect pathogens and related susceptibility traits, specifically looking at the impact of MRSA detection, and showed that the BioFire® FilmArray® Pneumonia panel has the potential to significantly expedite time to MRSA results allowing for rapid escalation or de-escalation of therapy.[85]

Based on the applicant's statements as presented previously, we are concerned there is insufficient information to determine whether the BioFire® FilmArray® Pneumonia Panel mechanism of action is different from existing products. In the FDA decision summary, the test is described as a multiplex nucleic acid test, or PCR accompanied by the applicant's software. However, it is unclear from the new technology add-on payment application how the mechanism of action is new or different from other products that utilize PCR. While the applicant described this test as the only sample-to-answer, rapid (~1 hour), and comprehensive molecular panel available for the diagnosis of the major causes of infectious pneumonia and as also semi-quantitative, and further described another comprehensive molecular product (Curetis Unyvero™) as having only bacterial targets and providing only qualitative results for all of its targets, we are uncertain how the underlying mechanism of action of the BioFire® FilmArray® Pneumonia Panel is different from existing PCR-based tests. Additionally, based on the information provided by the applicant, it appears as though the product does not treat a different disease or population compared to other products. Finally, with respect to the Furukawa study, which the applicant cited to support that the BioFire has the potential to specifically expedite time to MRSA results allowing for rapid escalation or de-escalation of therapy, we note that the study authors also concluded that the BioFire® FilmArray® Pneumonia Panel ''has good agreement with SOC for detection of bacteria and viruses'' and that the BioFire® FilmArray® Pneumonia Panel ''detects additional *S. aureus* bacteria not reported by SOC,'' but that ''[a]dditional *S. aureus* detection are more likely to be at low concentration and are of unclear clinical significance.'' We are inviting public comments on whether the BioFire® FilmArray® Pneumonia Panel is substantially similar to other technologies and whether the BioFire® FilmArray® Pneumonia Panel meets the newness criterion.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that the technology meets the cost criterion.

The applicant stated that it used 2018 data from Definitive Health Care at defhc.com, and that it searched these data for cases in MS–DRGs 193, 194, and 195 (Simple Pneumonia and Pleurisy with MCC, with CC, and without CC/MCC, respectively), which resulted in 297,956 cases. The applicant indicated that the data was from proprietary data drawn from one hospital in Indianapolis in 2018. However, the scope of the data as described by the applicant is unclear to us, as it seems unlikely that a single hospital in Indiana would have observed 297, 956 cases of simple pneumonia in 1 year. It is also not clear how these cases correspond to any of the later steps in the cost analysis. For example, the applicant did not indicate whether the charge values from the data are based on the same 297,956 cases identified in the three MS–DRGs.

In its analysis, the applicant stated that no charges were removed for any prior technologies as the BioFire® FilmArray® Pneumonia Panel does not eliminate culture testing of specimens. The applicant standardized the charges and then inflated the charges. The applicant reported using an inflation factor of 5.50 percent based on the charge inflation factor published by CMS in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42629). The applicant appears to have made a minor error in this inflation factor, since the actual, 1-year inflation factor in the FY 2020 IPPS/LTCH PPS final rule was 5.4 percent. To estimate the cost of the technology, the applicant used the per-test list price cost of the BioFire® FilmArray® Pneumonia Panel. The applicant indicated that it did not incorporate an estimate of technician time spent administering the test, asserting that ''2–5 minutes of technician time is nearly obsolete due to ease of use of the test.'' The applicant also indicated that it did not incorporate an estimate of instrumentation cost into its costing of the BioFire® FilmArray® Pneumonia Panel, noting that ''a number of'' labs already have sufficient instrumentation to run the BioFire® FilmArray® Pneumonia Panel test. The applicant added charges for the BioFire® FilmArray® Pneumonia Panel based on an estimated range of projected

[85] Furukawa, D., Kim, B., Jeng, A., BioFire® FilmArray® Pneumonia Panel: A Powerful Rapid Diagnostic Test for Antimicrobial Stewardship. Poster presented at Infectious Disease Week; 2019 October 2–6. Washington, DC.

patient charges for the BioFire® FilmArray® Pneumonia Panel technology. The applicant stated that the charge to the patient varies by location and the methodology of the hospital or lab charge master. The applicant noted that the estimate was based on patient charges for other BioFire products that had been reported by hospitals and reference labs. Based on this analysis, the applicant computed a final inflated average case-weighted standardized charge per case of $78,156, as compared to an average case-weighted threshold amount of $42,812. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

We are concerned that many of the calculated values in the applicant's analysis, such as the average-cost-per case, unweighted and unstandardized, were reportedly based on proprietary claims data that came from one hospital in Indianapolis. We are concerned that an analysis based on one hospital would not adequately represent the cost of cases using the BioFire® FilmArray® Pneumonia Panel as the data could be skewed or biased based on one hospital. We are also concerned with the lack of description of how the BioFire® FilmArray® Pneumonia Panel maps to the three MS–DRGs for simple pneumonia (that is, MS–DRGs 193, 194 and 195); for example, whether the analysis included all the cases in these MS–DRGs or was limited to specific cases. We note there are several additional pneumonia-related MS–DRGs to which we believe potential cases that may be eligible for the use of the product could be mapped, but which were not included in the cost analysis; for example, MS–DRGs 177, 178 and 179 (Respiratory Infections and Inflammations with MCC, with CC, and without CC/MCC, respectively) and MS–DRGs 974, 975, and 976 (HIV with Major Related Condition with MCC, with CC, and without CC/MCC, respectively).

We are inviting public comments on whether the BioFire® FilmArray® Pneumonia Panel meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that data from studies conducted with the BioFire® FilmArray® Pneumonia Panel show that it can detect major causes of pneumonia with a high degree of sensitivity and specificity in a clinically relevant timeframe. The applicant explained that results from the BioFire® FilmArray® Pneumonia Panel also have the potential to impact antibiotic usage and lead to improved stewardship and possible cost savings.

The applicant submitted four studies presented as posters at national conferences to support its assertion that the product represents a substantial clinical improvement, noting that data for this test is still new and has not yet been published in academic journals.

According to the applicant, Buchan, et al. compared the results of conventional testing (bacterial culture and clinician directed molecular testing for viruses and atypical bacteria) with the results from the BioFire® FilmArray® Pneumonia Panel for 259 BAL and 48 sputum samples.[86] We note that in their poster, Buchan, et al. specified that conventional testing specifically included bacterial culture and PCR based on clinician order. Also, while Buchan, et al. did report on the BAL specimens, the poster did not appear to report information regarding sputum samples. According to Buchan, et al., specimens were obtained from inpatients aged 18 years and older with symptoms of respiratory tract infection at 8 hospitals in the US. Chart review was conducted to determine type and duration of antibiotic therapy for each subject. According to the applicant, at least one bacterial pathogen was identified by standard methods and by the BioFire® FilmArray® Pneumonia Panel for 23 percent of BALs samples (n=60) and 35 percent (n=17) of sputum samples; however, the BioFire® FilmArray® Pneumonia Panel detected a bacterial pathogen in an additional 15 percent (n=40) of BAL samples and 21 percent (n=10) of the sputum samples. For the 259 BAL samples, 75 bacteria were identified by both standard methods and by the BioFire® FilmArray® Pneumonia Panel. The applicant noted that the BioFire® FilmArray® Pneumonia Panel identified an additional 84 bacteria, with the most common detections for *Staphylococcus aureus* (N=21), *Haemophilus influenzea* (n=19), *Moxaella catarrhalis* (n=8), *Pseudomonas aeruginosa* (n=6) and *Klebsiella oxytoca* (n=6). The applicant also explained that an evaluation of the medical and laboratory records for the affected patients found that 50 percent had been on antibiotics within 72 hours of samples collection, 42 percent of the organisms may have been present in the culture but were not reported (due either to low quantification ($<10^4$ cfu/mL) or the presence of mixed colonies) and only 8 percent of the detections were unexplained.

According to the applicant, an important feature of the BioFire® FilmArray® Pneumonia Panel is the inclusion of assays for viral agents. The applicant noted that in Buchan, et al., the BioFire® FilmArray® Pneumonia Panel identified at least 1 virus in 19 percent of 259 BAL samples from hospitalized adults[87] and viruses were the only pathogen detection in 12 percent (n=31) of BAL specimens, while 7 percent (n=18) had both bacterial and viral pathogen detections. The applicant summarized that the most common viral pathogens were human rhinovirus (n=17), coronavirus (n=9) and influenza (n=5). Twenty-three percent of the samples with a viral detection had a corresponding test ordered as part of standard of care. The applicant stated that this finding highlights that the role of viruses in pneumonia is still under appreciated. The applicant further stated that identification of a viral agent in the absence of a bacterial detection may allow reduction in the use of antibiotics.

According to the applicant, the ability of the BioFire® FilmArray® Pneumonia Panel to impact patient management has been evaluated by two different groups (Buchan, et al. and Enne, et al). The applicant stated that Buchan, et al., performed a theoretical outcomes analysis by using the result of the BioFire® FilmArray® Pneumonia Panel to modify antimicrobial therapy and then judge if the modification was correct using the final microbiology results. The applicant explained that in this analysis of 243 BAL samples, 68 percent (n=165) could have had an antibiotic adjustment; 48 percent (n=122) would have had antibiotics appropriately de-escalated or discontinued, 31 percent (n=78) would have had no change, and 2 percent (n=5) would have had appropriate escalation or initiation of antibiotics.[88] Alternately, 17 percent (n=42) would have received inappropriate escalation and 2 percent (n=6) would have received inappropriate de-escalation when compared to culture results. The applicant summarized that the most common de-escalations occurred due to discontinuation of vancomycin due to non-detection of MRSA (35 percent) and discontinuation of piperacillin/tazobactam due to non-detection of *Enterobacteriaceae* (23 percent).

[86] Buchan, B.W., Windham, S., Faron, M.L., et al. Clinical Evaluation and Potential Impact of a Semi-Quantitative Multiplex Molecular Assay for the Identification of Pathogenic Bacteria and Viruses in Lower Respiratory Specimens. Poster presented at American Thoracic Society; 2018 May 02. San Diego, CA.

[87] Ibid.

[88] Ibid.

According to the applicant, the de-escalation due to non-detection of these pathogens is possible because the increased sensitivity of the BioFire® FilmArray® Pneumonia Panel for detection of bacterial pathogen provides a high negative predictive value for these non-detections. The applicant explained that the authors estimated the results could have potentially saved >18,000 antibiotic hours equating to an average of 6.5 days/patient (we note that in the poster by Buchan, et al., they reported an average of 6.2 d/patient rather than 6.5 mentioned in the application).[89]

According to the applicant, in an analysis of 120 ICU patients (79 males and 41 females; 33 children, with a median age of 1; and adults with a median age of 68) in the UK by Enne, et al., patients were divided into a group with positive outcomes (pneumonia resolved within 21 days) and negative outcomes (pneumonia not resolved in 21 days or contributed to the patient's death). Enne, et al., evaluated the appropriateness of antimicrobials used for HAP/VAP versus both routine culture and two rapid PCR tests, BioFire® FilmArray® Pneumonia Panel (1h) and Curetis Unyvero™ Pneumonia Panel (5.5h). Consented or assented ICU patients were recruited at 4 diverse UK hospitals: 1 district general, 1 tertiary referral, 1 children's and 1 private. Patients were those starting or changing antibiotics for suspected pneumonia, already hospitalized for >48h and with a timely respiratory sample. According to the applicant, the results of the BioFire® FilmArray® Pneumonia Panel and routine culture were evaluated to determine if the test results would have identified the antibiotic therapy as active or inactive. The applicant explained that in the group with positive outcomes, the results of the BioFire® FilmArray® Pneumonia Panel were able to correctly classify the patient's therapy as active for 35 percent of patients compared to only 20 percent for routine culture (p=0.005). The applicant also explained that in the group of 27 percent of patients that had negative outcomes, the results of the BioFire® FilmArray® Pneumonia Panel would have classified the initial antibiotic therapy as inactive for 41 percent of patients compared to only 15.6 percent for routine culture.[90] The study authors also reported that routine microbiology and Curetis Unyvero™ detected a potential pathogen in 41.7 percent and 59.2 percent of specimens respectively, whereas BioFire® FilmArray® Pneumonia Panel detected a potential pathogen in 66.7 percent of respiratory samples from patients enrolled in the study. The applicant stated that these study results indicate that the test results of the BioFire® FilmArray® Pneumonia Panel provide information that can lead to more targeted and effective therapy in a shorter period of time, and may help to improve patient outcomes.

The applicant also submitted Rand et al., which conducted a retrospective analysis of BAL (n=197) and endotracheal aspirates (n=93) samples from 270 unique hospitalized patients that were collected and stored at −70 °C until thawed and tested on the BioFire® FilmArray® Pneumonia Panel compared to routine microbiology results.[91] Patient data were extracted from the electronic medical record. Cultures were performed by standard methods and identified by Vitek II and mass spectrometry. The applicant explained that the authors found a high correlation between standard methods and BioFire® FilmArray® results and that the authors concluded the BioFire® FilmArray® Pneumonia Panel would have had a significant impact on time to result which could potentially lead to more rapid and appropriate use of antibiotics. The applicant also noted that the authors found significant association with clinical/outcome variables and that the BioFire® FilmArray® Pneumonia Panel's semi-quantification was ''at least as strong'' as standard culture methods, which according to the applicant, have been developed and improved over decades.

The applicant also submitted White et al., which conducted a comparison of the BioFire® FilmArray® Pneumonia Panel on sputum samples to a multi-test diagnostic bundle for patients admitted from the emergency department (ED) with community acquired pneumonia (CAP).[92] We note that White et al., specifically described the diagnostic bundle as including the following: (1) Blood Cultures; (2) Sputum culture and sensitivity; (3) Urine antigens: *Legionella and S. pneumoniae*; (4) Nasal swab (NS) PCR for *MRSA* and *S. pneumoniae*; (5) FilmArray (Biofire) PCR Panel (NS): Detects 17 viruses, 4 bacteria. Of 585 enrolled patients, 278 were evaluable. The applicant explained that the authors found that the BioFire® FilmArray® Pneumonia Panel detected a higher rate of potential pathogens than the multi-test bundle (90.6 percent versus 81 percent). The applicant also noted that the authors determined that the urine antigen testing, *S. aureus* and *S. pnuemoniae,* and PCR upper respiratory panel use could be eliminated for this sample/patient type in the future.[93]

The applicant also submitted a poster by Furukawa et al., which reported a retrospective case review of 43 samples (17 used for clinical use and 26 obtained randomly by microbiology lab) in which BioFire® FilmArray® Multiplex PCR was utilized.[94] According to the applicant, initial use of BioFire FilmArray Pneumonia panel had 100 percent intervention rate leading to de-escalation or prevention of inappropriate antibiotics and the authors found that there was a low risk of unnecessary antibiotics being administered due to the increased sensitivity of the BioFire® FilmArray® Pneumonia panel. The applicant added that the authors believe that with additional data they may be able to discontinue empiric broad spectrum coverage due to the rapid and sensitive nature of the BioFire FilmArray Pneumonia Panel. The applicant also noted that they have a number of ongoing prospective studies being conducted to further support their claims.

The applicant asserted that Buchan, et al. and Rand et al. support their claim of decreased time to actionable results based on— (1) the conclusion in Buchan, et al., that greater than 60 percent of patients potentially could have had an antibiotic adjustment 3–4 days earlier than standard methods based on BioFire® FilmArray® Pneumonia Panel results, and (2) the conclusion in Rand et al., that the BioFire® FilmArray® Pneumonia Panel would have a major impact on the time to report potential pathogens that may cause Pneumonia in intubated/ICU patients.

The applicant asserted that Buchan, et al., and Enne V.I. et al. support their

[89] Ibid.

[90] Enne, V.I., Baldan, R., Russell, C., et al. INHALE WP2: Appropriateness of Antimicrobial Prescribing for Hospital-acquired and Ventilator-associated Pneumonia (HAP/VAP) in UK ICUs assessed against PCR-based Molecular Diagnostic Tests. Poster presented at European Congress of Clinical Microbiology and Infectious Disease; 2019 April 13–16. Amsterdam, Netherlands.

[91] Rand, K.H., Beal S.G., Cherabuddi, K., et al. Relationship of a Multiplex Molecular Pneumonia Panel (PP) Results with Hospital Outcomes and Clinical Variables. Poster presented at Infectious Disease Week; 2019 October 2–6. Washington, DC.

[92] White, E., Ferdosian, S., Gelfer, G., et al., Sputum FilmArray Pneumonia Panel Outperforms A Diagnostic Bundle in Hospitalized CAP Patients. Poster presented at Infectious Disease Week; 2019 October 2–6. Washington, DC.

[93] Ibid.

[94] Furukawa, D., Kim, B., Jeng, A., BioFire® FilmArray® Pneumonia Panel: A Powerful Rapid Diagnostic Test for Antimicrobial Stewardship. Poster presented at Infectious Disease Week; 2019 October 2–6. Washington, DC.

claim of improved antibiotic stewardship. The applicant pointed to the conclusions in Buchan, et al., that >60 percent of patients potentially could have had an antibiotic adjustment with BioFire® FilmArray® Pneumonia Panel results and 50 percent of potential antibiotic adjustments from BioFire® FilmArray® Pneumonia Panel testing were discontinuation or narrowing, as well as the estimate that the BioFire® FilmArray® Pneumonia Panel results enabled >18,000 antibiotic hours saved on 243 patients. The applicant pointed to Enne V.I. et al., for the results that of the 27 percent of patients who had negative outcomes, 15.6 percent had a pathogen resistant to initial therapy based on culture and 41.9 percent were resistant to initial therapy based on BioFire® FilmArray® Pneumonia Panel results (p=0.029).

The applicant asserted that White E., et al., and Enne, et al. support its claim of increased diagnostic yield because White et al. concluded that of patients with a final diagnosis of pneumonia, BioFire® FilmArray® Pneumonia Panel detected a potential pathogen in 90.6 percent compared to 81 percent with standard methods, and Enne, et al. reported that routine methods detected a pathogen in 41.7 percent of specimens compared to the BioFire® FilmArray® Pneumonia Panel which detected a pathogen in 66.7 percent of specimens.

In summary, the applicant explained that lower respiratory tract infections are a common and serious health care problem, current diagnostic tests are slow and do not identify a causative pathogen in over 50 percent of patients, and the BioFire® FilmArray® Pneumonia Panel is an easy-to-use multiplex panel that has been shown to increase diagnostic yield and significantly decrease time to results when compared to standard testing both because of improved test sensitivity and because it includes assays for typical bacteria, viruses and selected antibiotic resistance genes. According to the applicant, retrospective review of BioFire® FilmArray® Pneumonia Panel and patient data indicates a potential to impact antibiotic utilization to ensure patients are on appropriate therapy in a timely manner. The applicant also noted that molecular testing for pneumonia is relatively new and there is a lot to learn about how to best use these tests, and that there are currently several prospective studies underway to clarify the role that this tool may play in improving the outcomes for patients with pneumonia, reducing use of unnecessary antibiotics, improving targeted therapy and potentially reducing health care costs due to more directed and efficient patient management. According to the applicant, early theoretical outcomes evaluations provide reason to be optimistic.

We note that the studies the applicant submitted to support its assertions regarding substantial clinical improvement were presented only as posters, and that information pertaining to full manuscripts with further study details were not provided. It is also unclear if the studies described in the posters have been submitted for peer-reviewed publication or whether full manuscripts with detailed methods and data tables are available.

We are concerned that the studies do not appear to be designed or powered to be able to show conclusive evidence of clinical impact. In particular, the studies appear to describe analysis of clinical results for patients and state that there is potential for the results to impact clinical decisions about antimicrobial therapy. However, it appears the applicant did not submit evidence of the BioFire® FilmArray® Pneumonia Panel product in real world, prospective use (randomized or non-randomized) with actual antimicrobial decisions or effect on patient management. This may require larger sample sizes. We are also concerned that only one study provided by the applicant (Enne, V.I., et al.) compared BioFire® FilmArray® Pneumonia Panel to Curetis Unyvero™, which is another PCR-based technology, and that a statistical difference was not reported between BioFire and Unyvero for the outcomes reported in the poster. While we understand that Curetis Unyvero™ may be somewhat slower than BioFire® FilmArray® Pneumonia Panel and does not include viruses, the clinical impact of the differences between these two products is unclear. We are also uncertain how Buchan, et al. calculated their estimate that >18,000 antibiotic hours were saved on 243 patients using the BioFire® FilmArray® Pneumonia Panel results. The applicant stated that there are currently several prospective studies underway to clarify the role that this tool may play in improving the outcomes for patients with pneumonia, reducing use of unnecessary antibiotics, improving targeted therapy and potentially reducing health care costs due to more directed and efficient patient management; however, data or results from those studies were not included with the application.

We welcome public comment on whether the BioFire® FilmArray® Pneumonia Panel meets the substantial clinical improvement criterion.

We did not receive any written public comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for the BioFire® FilmArray® Pneumonia Panel or at the New Technology Town Hall meeting.

c. ContaCT

Viz.ai Inc. submitted an application for new technology add-on payments for ContaCT for FY 2021. The individual components of ContaCT are currently marketed by Viz.ai, Inc. under the tradenames ''Viz LVO'' (for the algorithm), ''Viz Hub'' (for the text messaging and calling platform), and ''Viz View'' (for the mobile image viewer). According to the applicant, ContaCT is a radiological computer-assisted triage and notification software system intended for use by hospital networks and trained clinicians. The applicant asserted that ContaCT analyzes computed tomography angiogram (CTA) images of the brain acquired in the acute setting, sends notifications to a neurovascular specialist(s) that a suspected large vessel occlusion (LVO) has been identified, and recommends review of those images.

The applicant asserted early notification of the stroke team can reduce time to treatment and increase access to effective specialist treatments, like mechanical thrombectomy. Specifically, the applicant asserted that shortening the time to identification of LVO is critical because the efficacy of thrombectomy in patients with acute ischemic stroke decreases as the time from symptom onset to treatment increases. The applicant also asserted in a condition like stroke, where 1.9 million neurons die every minute and for which 34 percent of patients hospitalized are under the age of 65, reducing time to treatment results in reduced disability.[95] The applicant asserted ContaCT streamlines the standard workflow using artificial intelligence to substantially shorten the period of time between when a patient receives a stroke CT/CTA and when the patient is referred to a stroke neurologist and neurointerventional surgeon.

With respect to the newness criterion, according to the applicant, FDA granted marketing authorization to ContaCT on February 13, 2018 under the *de novo* pathway, which is only available to devices of a new type with low-to-

[95] Hall MJ, Levant S, DeFrances CJ. Hospitalization for stroke in U.S. hospitals, 1989–2009. NCHS data brief, no 95. Hyattsville, MD: National Center for Health Statistics. 2012. *https://www.cdc.gov/nchs/data/databriefs/db95.pdf.*

moderate risk for which there are no legally marketed predicates, and classified it as a Class II medical device. We note that FDA issued a *de novo* order memorandum describing ContaCT as ''an artificial intelligence algorithm [used] to analyze images for findings suggestive of a pre-specified clinical condition and to notify an appropriate medical specialist of these findings in parallel to standard of care image interpretation.'' The order specified that ''identification of suspected findings is not for diagnostic use beyond notification.''

The applicant asserted ContaCT was not available immediately after FDA's marketing authorization due to establishing Quality Management Systems and processes for distributing ContaCT as well as staff training and installation. Per the applicant, ContaCT was not commercially available until October 2018.

We note the applicant has submitted a request to the ICD–10 Coordination and Maintenance Committee for approval for a unique ICD–10–PCS procedure code, effective in FY 2021, to describe procedures that use ContaCT. Currently, there are no ICD–10–PCS procedure codes to uniquely identify procedures involving the use of ContaCT.

As discussed above, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant asserted no existing technology is comparable to ContaCT. The applicant further asserted, because of the technology's novelty, the product was reviewed under FDA's *de novo* pathway. The applicant first outlined the clinical workflow for patients presenting to a hospital with signs or symptoms of LVO prior to the availability of ContaCT:

1—Patient presents with stroke/suspected stroke to hospital emergency department (ED).
2—Patient receives stroke CT/CTA imaging after brief initial evaluation by hospital ED physician.
3—Technologist processes and reconstructs the CT/CTA imaging and manually routes to hospital picture archiving and communication system (PACS).
4—Radiologist reads CT/CTA imaging.
5—If needed, a neuroradiology consult is sought.
6—A radiological diagnosis of LVO is made.
7—The radiologist informs hospital ED physician of positive LVO either verbally or in the radiologist report.
8—ED physician performs comprehensive exam and refers the patient to a stroke neurologist.
9—The stroke neurologist reviews the CT/CTA imaging and clinical history and determines whether to prescribe or recommend prescription of thrombolysis with tissue plasminogen activator (tPA).
10—The stroke neurologist refers the patient to a neurointerventional surgeon. Together they decide whether the patient is a candidate for mechanical thrombectomy.
11—If appropriate, the patient proceeds to treatment with mechanical thrombectomy.

The applicant asserted that facilities utilizing the ContaCT system can substantially shorten the period of time between when the patient receives stroke CT/CTA imaging (step 2) and when the patient is referred to a stroke neurologist and neurointerventional surgeon (steps 9 and 10). They further assert that ContaCT streamlines this workflow using artificial intelligence to analyze CTA images of the brain automatically and notifies the stroke neurologist and neurointerventional surgeon that a suspected LVO has been identified, and then enables them to review imaging and make a treatment decision faster. The applicant concludes that shortening the time to identification of LVO is critical because the efficacy of thrombectomy in patients with acute ischemic stroke decreases as the time from symptom onset to treatment increases.

With regard to the second criterion, whether the technology is assigned to the same or a different MS–DRG, the applicant did not specifically address whether the technology meets this criterion. However, we believe that cases involving the use of the technology would be assigned to the same MS–DRGs as cases without the technology where the patient moves through the hospital according to the traditional workflow outlined above.

With regard to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant also did not specifically address whether the technology meets this criterion. However, we believe cases involving the use of the technology would treat the same or similar type of disease and the same or similar patient population as the traditional workflow outlined above.

We note that the applicant described ContaCT's mechanism of action as shortening the time to identification of LVO through artificial intelligence (AI). Specifically, the applicant asserted that facilities utilizing the ContaCT system can substantially shorten the period of time between when the patient receives stroke CT/CTA imaging and when the patient is referred to a stroke neurologist and neurointerventional surgeon. We are unclear as to whether the streamlining of hospital workflow would represent a unique mechanism of action. Rather, it seems that the mechanism of action for ContaCT would be the use of AI to analyze images and notify physicians rather than streamlining hospital workflow. However, we refer the reader to our discussion below regarding our concerns with respect to general parameters for identifying a unique mechanism of action based on the use of AI, an algorithm and/or software.

To the extent that the applicant asserted that streamlined hospital workflow through the use of ContaCT represents a unique mechanism of action, it is unclear to us the degree to which ContaCT changes the traditional workflow. Per the FDA, ''ContaCT is limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to confirm diagnosis.'' [96] It is unclear to CMS how ContaCT shortens time to treatment via AI if the CT machine still performs the scanning and clinicians are still needed to view the images to diagnose an LVO and perform a full patient evaluation for the best course of treatment. The applicant has also indicated to CMS that the use of ContaCT is not automatic, and the E.R. physician must submit an order to utilize it specifically when suspecting an LVO. We are unclear how ContaCT streamlines the workflow for stroke treatment via AI if it is not to be used for diagnostic purposes per the FDA and still requires personnel to order the scan and make the diagnosis.

We also are generally concerned as to whether the use of AI, an algorithm, or software, which are not tangible, may be considered or used to identify a unique mechanism of action. In addition, we question how updates to AI, an algorithm or software would affect an already approved technology or a competing technology, including whether software changes for an already approved technology could be

[96] U.S. Food and Drug Administration, DEN170073. *Evaluation of Automatic Class III Designation for ContaCT Decision Summary.*

considered a new mechanism of action. We also question whether, if there were competing technologies to an already approved AI new technology, an improved algorithm by a competitor would represent a unique mechanism of action if the outcome is the same as the technology first approved. We welcome comments from the public regarding the general parameters for identifying a unique mechanism of action based on the use of AI, an algorithm and/or software.

We also invite public comments on whether the applicant meets the newness criterion, including specifically with respect to the mechanism of action.

With respect to the cost criterion, the applicant provided the following analysis. First, the applicant extracted claims from the FY 2018 MedPAR dataset. The applicant explained that many patients present to the emergency department with signs or symptoms suggesting a LVO. That presentation would be the basis for ordering a CTA with the ContaCT added. Of these patients, some will be identified as stroke and LVO, some as stroke but not from a LVO, and others will have diagnoses completely unrelated to stroke. As a result, according to the applicant, there may be a very broad range of principal diagnoses and MS–DRGs representing patients who would be eligible for and receive a CTA with ContaCT. The applicant noted that it used admitting diagnoses codes rather than principal or secondary diagnosis codes to identify cases of stroke due to LVO, stroke not due to LVO, and no stroke. The applicant utilized a multi-step approach:

- Step 1: The applicant first extracted claims from the stroke-related MS–DRGs (023, 024, 061, 062, 063, 064, 065, 066, 067, 068, and 069).
- Step 2: The applicant analyzed the admitting diagnosis on claims extracted in Step 1 to identify the reason for admission. The applicant found that the top five admitting diagnoses for patients in the stroke-related MS–DRGs included: Cerebral infarction, unspecified (I63.9), transient cerebral ischemic attack, unspecified (G45.9), slurred speech (R4781), aphasia (R4701), and facial weakness (R29.810).
- Step 3: The applicant identified all MS–DRGs assigned to the admitting diagnosis codes identified in step 2 to identify ContaCT cases that did not map to one of the stroke MS–DRGs.
- Step 4: The applicant identified a list of unique MS–DRGs and admitting diagnosis code combinations to which cases involving ContaCT would map. The applicant stated that it reviewed with clinical experts the MS–DRG and admitting diagnosis combinations and eliminated any that were unlikely to include the use of ContaCT.

The applicant identified a total of 375,925 cases across 143 MS–DRGs, with approximately 66% of cases mapping to MS–DRGs 039, 057, 064, 065, 066, 069 and 312. The average unstandardized case-weighted charge per case was $52,001. The applicant noted it did not remove any charges for a prior technology, as it asserted that no other technology is comparable to ContaCT. Based on the results of a research study,[97] the applicant assumed ContaCT cases resulting in mechanical thrombectomy would have charges reduced by 38% as a result of reduced specialty care days and therefore removed the related charges, which only affected cases mapping to MS–DRGs 023, 024, 025, and 026. The applicant standardized the charges and applied an inflation factor of 11.1%, which is the same inflation factor used by CMS to update the outlier threshold in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42629), to update the charges from FY 2018 to FY 2020.

The applicant then added the charges for the new technology. The applicant explained it calculated the cost per patient by dividing the total overall cost of ContaCT per year per hospital by the number of total estimated cases for which ContaCT was used at each hospital that currently subscribes to ContaCT (based on the estimated number of cases receiving CTA), and averaging across all such hospitals. The following is the methodology the applicant used to determine the cost per case:

- *Step 1:* The applicant first determined the estimated total cases (both Medicare and non-Medicare) for each current subscriber hospital. The applicant explained it used total cases for both Medicare and non-Medicare cases since the cost per case is not specific to Medicare cases. In order to determine total cases, which include both Medicare and non-Medicare cases, the applicant divided the total Medicare cases per subscriber hospital from the FY 2018 MedPAR data by the percentage of Medicare beneficiaries (71 percent) in the CONTACT FDA research study (for example, 1,136 Medicare cases divided by 0.71 equals 1,600 total Medicare and non-Medicare cases).
- *Step 2:* To analyze actual rates (percentages) of CTA across subscriber hospital cases, the applicant first used the beneficiary ID in the FY 2018 SAF data set to find matching physician claims in the carrier file for CT and CTA services with a site of service of 21 (Inpatient hospital) or 23 (emergency department) and a date of service consistent with the inpatient stay. The applicant then calculated provider-specific CTA rates (percentages) for each subscriber hospital. The applicant dropped five hospitals with a low volume of Medicare inpatient stays that had no matching services in the carrier file. The applicant calculated an average CTA rate of 21.6 percent across all hospitals that subscribe to ContaCT.
- *Step 3:* The applicant determined the estimated total number of cases that received CTA for each current subscriber hospital by multiplying the total cases (Medicare and non-Medicare) for each subscriber hospital in step 1 by the provider-specific CTA rate calculated in Step 2. In cases where a provider had fewer than 11 cases in the carrier file or where a provider had a CTA rate that was an outlier, the applicant multiplied the total cases for the provider by the average CTA rate of 21.6 percent.
- *Step 4:* The applicant then calculated the cost per year per hospital. If a hospital had multiple sites under the same CCN, the applicant multiplied the total overall cost of ContaCT per hospital by the number of sites. For example, if the cost for ContaCT was $25,000 per year and Hospital A had only one site under its CCN, then the total cost for ContaCT for Hospital A would be $25,000. However, if Hospital B had three sites under its CCN, then the total cost for ContaCT for Hospital B would be $75,000 per year ($25,000 × 3).
- *Step 5:* The applicant then divided the cost per year per hospital by the total cases that received CTA for each customer hospital in step 3 to determine the estimated cost per case for each customer hospital. If Hospital A from the example in Step 4 had 50 patients, then the total hospital cost per case would be $500 per patient ($25,000/50). If Hospital B (with three sites under its CCN) also had 50 patients, then the total hospital cost per case would be $1,500 per patient ($75,000/50).
- *Step 6:* The applicant averaged the cost per case across all hospitals to determine the average cost per patient. The average cost per case across Hospital A and Hospital B in the previous example would be $1,000.
- *Step 7:* To convert the cost of the technology in Step 6 to charges, the applicant divided the average cost per patient by the national average cost-to-

[97] Goldstein ED, Schnusenberg L, Mooney L, et al. Reducing Door-to-Reperfusion Time for Mechanical Thrombectomy With a Multitiered Notification System for Acute Ischemic Stroke. Mayo Clin Proc Innov Qual Outcomes. 2018;2(2): 119–128.

charge (CCR) of 0.14 for the Radiology cost center from the FY 2020 IPPS/LTCH PPS final rule. (84 FR 42179). Although the applicant submitted data related to the cost of the technology, the applicant noted that the cost of the technology was proprietary information.

The applicant calculated a case-weighted threshold amount of $51,358 and a final inflated average case-weighted standardized charge per case of $62,006. Based on this analysis, the applicant believes that ContaCT meets the cost criterion because the final inflated average case-weighted standardized charge per case exceeds the case-weighted threshold amount.

The applicant submitted three additional cost analyses to demonstrate that it meets the cost criterion using the same methodology above but with limits on the cases. The first alternative limited the analysis to only those cases in the primary stroke-related MS–DRGs 023, 024, 061, 062, 063, 064, 065, 066, 067, 068, and 069. This first alternative method resulted in a case-weighted threshold of $53,885 and a final inflated average case weighted standardized charge per case of $62,175. The second alternative limited the analysis to cases in MDC 01 (Diseases and Disorders of the Nervous System) with the following MS–DRGs:

MS-DRG	MS-DRG Description
023	Craniotomy with Major Device Implant or Acute Complex CNS PDX with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator
024	Craniotomy with Major Device Implant or Acute Complex CNS PDX without MCC
025-027	Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively
037-039	Extracranial Procedures with MCC, with CC, and without CC/MCC, respectively
061-063	Ischemic Stroke, Precerebral Occlusion or Transient Ischemia with Thrombolytic Agent with MCC, with CC, and without CC/MCC, respectively
064-066	Intracranial Hemorrhage or Cerebral Infarction with MCC, with CC or TPA in 24 hours, and without CC/MCC, respectively
067-068	Nonspecific CVA and Precerebral Occlusion without Infarction with and without MCC, respectively
069	Transient Ischemia without Thrombolytic
091-093	Other Disorders of Nervous System with MCC, with CC, and without CC/MCC, respectively

This second alternative method resulted in a case-weighted threshold of $55,053 and a final inflated average case weighted standardized charge per case of $63,741. The third alternative limited cases to MS–DRGs where the total volume of cases was greater than 100. This third alternative method resulted in a case-weighted threshold of $49,652 and a final inflated average case weighted standardized charge per case of $59,365. Across all cost-analysis methods, the applicant maintained that the technology meets the cost criterion because the final inflated average case weighted standardized charge per case exceeds the average case-weighted threshold amount.

We note that we believe a case weight would provide more accuracy in determining the average cost per case as compared to the average of costs per case across all hospitals that was used by the applicant in step 6 as summarized previously. We therefore computed a case weighted cost per case across all current subscriber hospitals. We then inflated the case weighted cost per case to a charge based on step 7 above and used this amount in the comparison of the case weighted threshold amount to the final inflated average case weighted standardized charge per case (rather than the applicant's average cost per case). In all the scenarios above, the final inflated average case-weighted standardized charge per case exceeded the case-weighted threshold amount by an average of $2,961.

We have the following concerns regarding whether the technology meets the cost criterion. The applicant used a single list price of ContaCT per hospital with a cost per patient that can vary based on the volume of cases. We are concerned that the cost per patient varies based on the utilization of the technology by the hospitals. The cost per patient could be skewed by the small number of hospitals utilizing the technology and their low case volumes. It is possible, if hospitals with large patient populations adopt ContaCT, the cost per patient would be significantly lower.

An alternative to the applicant's calculation may be a methodology that expands the applicant's sample from total cases (which include both Medicare and non-Medicare cases) receiving CTA at subscriber hospitals in Step 1 to all inpatient hospitals for the use of ContaCT (and then using the same steps after Step 1 for the rest of the analysis). In this alternative, the applicant would continue to extract cases representing patients that are eligible for the use of ContaCT from MedPAR, but the cost per patient would be determined by dividing the overall cost per year per hospital by the average number of patients eligible for the use of ContaCT across all such hospitals. For example, if the cost for ContaCT is $25,000 per year and the average hospital has 500 patients who are eligible to receive ContaCT per year, then under this alternative methodology, the total cost per patient would be $50 ($25,000/500).

We note, if ContaCT were to be approved for new technology add-on payments for FY 2021, we believe the cost per case from the cost analysis above may also be used to determine the maximum new technology add on payment (that is, 65 percent of the cost determined above). We understand there are unique circumstances to determining a cost per case for a technology that utilizes a subscription for its cost. We welcome comments from the public as to the appropriate method to determine a cost per case for such technologies, including comments on whether the cost per case should be estimated based on subscriber hospital data as described previously, and if so,

whether the cost analysis should be updated based on the most recent subscriber data for each year for which the technology may be eligible for the new technology add-on payment.

We also invite public comments on whether the applicant meets the cost criterion.

With respect to the substantial clinical improvement criterion, according to the applicant, ContaCT represents an advance that substantially improves the ability to diagnose a large vessel occlusion stroke earlier by automatically identifying suspected disease in CTA images and notifying the neurovascular specialist in parallel to the standard of care. The applicant further asserted a major limitation in the traditional acute stroke workflow is the time delay from initial image acquisition of a suspected LVO patient (CT, CT angiography, and CT perfusion), notification of the interventional team, and execution of an endovascular thrombectomy. The time from stroke onset to reperfusion (tissue damage caused when blood supply returns to tissue after a period of ischemia or lack of oxygen) is negatively correlated with the probability of an independent functional status.[98] The applicant states the time from initial presentation to eventual reperfusion can be long, resulting in poor outcomes, using the existing standard of care. The median onset-to-revascularization time has been reported as 202.0 minutes for patients presenting directly to interventional centers (or comprehensive stroke centers), and 311.5 minutes for patients that initially presented to a non-interventional center.[99] The applicant further states that part of that time is the time from initial CTA-scan to the time that the neurovascular specialist is notified of a possible LVO (the CTA to notification time). A retrospective study examined work-flow for stroke patients and demonstrated an initial CT to CSC (Comprehensive Stroke Center) notification time per standard of care >60 minutes in patients transferred for endovascular reperfusion in acute ischemic stroke.[100]

The applicant asserted that ContaCT facilitates a workflow parallel to the standard of care workflow and results in a notified specialist entering the workflow earlier. In a study comparing the performance of ContaCT with standard of care workflow, ContaCT resulted in faster specialist notification. According to the applicant, the average time to specialist notification for ContaCT was 7.32 minutes [95%CI: 5.51, 9.13] whereas time to notification for standard of care workflow was 58.72 minutes [95%CI: 46.21, 71.23]. The applicant also asserted that ContaCT saved an average of 51.4 minutes, an improvement that could markedly improve time to intervention for LVO patients. In addition, the applicant noted that the standard deviation was reduced from 41.14 minutes in the standard of care workflow to 5.95 minutes with ContaCT, demonstrating ContaCT's potential to reduce variation in care and patient outcome across geographies and time of day.[101]

To support the applicant's assertion that ContaCT substantially improves the ability to diagnose a large vessel occlusion stroke earlier, the applicant presented a multicenter prospective observational trial, DISTINCTION, which is ongoing and compares a prospective cohort of patients in which ContaCT is used (intervention arm) to a retrospective cohort in which ContaCT was not used (control arm). Patients are also segmented based on whether they initially present to a non-interventional center or an interventional center. Per the applicant, early data from one non-interventional hospital in the Erlanger Health System indicates that for the control arm the median time from CTA to clinician notification was 59.0. For the intervention arm, early data indicates that the median time from CTA to clinician notification was 5.3 min. The applicant stated that these early data indicate time savings of approximately 53 min, which is consistent with the 51.4 min. time savings demonstrated in the studies sponsored/conducted by the De Novo requester.[102]

Next, the applicant presented the Automated Large Artery Occlusion Detection In Stroke Imaging Study (ALADIN), a multi-center retrospective analysis of CTAs randomly picked from a retrospective cohort of acute ischemic stroke patients, with and without anterior circulation LVOs, admitted at three tertiary stroke centers, from 2014–2017. Per the applicant, ALADIN evaluated ContaCT's performance characteristics including area under the curve, sensitivity, specificity, positive predictive value, negative predictive value, and processing or running time. The applicant asserted that, through this study, researchers concluded that the ContaCT algorithm may permit early and accurate identification of LVO stroke patients and timely notification to emergency teams, enabling quick decision-making for reperfusion therapies or transfer to specialized centers if needed.[103] [104] [105]

According to the applicant, the use of ContaCT to facilitate a faster diagnosis and treatment decision directly affects management of the patient by enabling early notification of the neurovascular specialist and faster time to treatment utilizing mechanical thrombectomy to remove the large vessel occlusion. The applicant stated that mechanical thrombectomy with stent retrievers is one of the standards of care for treatment of acute ischemic stroke patients caused by LVO and that mechanical thrombectomy therapy is highly time-critical with each minute saved in onset-to-treatment time resulting in a reported average of 4.2 days of extra healthy life.[106] According to the applicant, the use of ContaCT affects the management of the patient by facilitating early identification of patients with suspected LVO and early notification of the neurovascular specialist. The applicant asserted that

[98] Khatri P, Abruzzo T, Yeatts SD, et al. Good clinical outcome after ischemic stroke with successful revascularization is time-dependent. *Neurology.* 2009;73(13):1066–1072.

[99] Froehler MT, Saver JL, Zaidat 00, et al. Interhospital transfer before thrombectomy is associated with delayed treatment and worse outcome in the STRATIS registry. *Circulation.* 2017; 136(24):2311–2321.

[100] Sun CH, Nogueira J, Glenn RG, et al. Picture-to-puncture: A novel time metric to enhance outcomes in patients transferred for endovascular reperfusion in acute ischemic stroke. *Circulation.* 2013;127:1139–1148.

[101] U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. Evaluation of Automatic Class III Designation for ContaCT. Decision Memorandum No. 170073 (DEN170073). 2018. Retrieved from: *https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170073.pdf.*

[102] U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. Evaluation of Automatic Class III Designation for ContaCT. Decision Memorandum No. 170073 (DEN170073). 2018. Retrieved from: *https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170073.pdf.*

[103] Barreira C, Bouslama M, Lim J, et al. E–108 ALADIN study: Automated large artery occlusion detection in stroke imaging study—a multicenter analysis. *J Neurointerv Surg.* 2018;10(Suppl 2):A101–A102.

[104] Barreira C, Bouslama M, Haussen D, et al. Abstract WP61: Automated large artery occlusion detection in stroke imaging—ALADIN study. *Stroke. 2*018;49:AWP61.

[105] Rodrigues GM, Barreira CM, Bouslama M, et al. Automated large artery occlusion detection in stroke imaging study (ALADIN). Abstract WP71: Multicenter ALADIN: Automated large artery occlusion detection in stroke imaging using artificial intelligence. *Stroke.* 30 Jan 2019;50:AWP71.

[106] Fransen PS, Berkhemer OA, Lingsma HF, et al. Time to reperfusion and treatment effect for acute ischemic stroke: A randomized clinical trial. *JAMA Neurol.* 2016;73:190–196; Meretoja A, Keshtkaran M, Tatlisumak T, Donnan GA and Churilov L. Endovascular therapy for ischemic stroke: Save a minute—save a week. *Neurology.* 2017;88(22):2123–2127.

this may affect the management of the patient in two ways. First, it may offer improved access to mechanical thrombectomy for patients who would otherwise not have access because of factors such as time of day and the specialty capabilities of the hospital they are in, and second, it may involve the neurovascular team earlier, decreasing the time to thrombectomy. The applicant stated that ContaCT saved an average of 51.4 minutes in time to notification relative to standard of care workflow and reduced standard deviation in time to notification from 41.14 minutes (standard of care workflow) to 5.95 minutes (ContaCT).[107] Furthermore, the applicant stated that ContaCT could markedly improve time to intervention for LVO patients and has the potential to reduce variation in care and patient outcome across geographies and time of day.

The applicant stated that according to five clinical trials, the clinical efficacy of endovascular mechanical thrombectomy has been demonstrated for patients with LVO strokes up to 6 hours after onset of stroke.[108] The applicant also stated that two meta-analyses of these randomized trials have been completed.[109] Campbell et al., performed a patient-level pre-specified pooled meta-analysis of four randomized clinical trials which concluded that thrombectomy for large vessel ischemic stroke is safe and highly effective at reducing disability. Goyal et al., pooled and analyzed patient-level data from all five trials. Per the applicant, the results indicated that mechanical thrombectomy leads to significantly reduced disability. According to the applicant, together, these five randomized trials and two meta-analyses, have demonstrated that treatment for intracranial large vessel occlusion with mechanical thrombectomy with stent retrievers is the standard of care.

The applicant also asserted that real world evidence further supports the efficacy of mechanical thrombectomy. Data from the STRATIS registry (Systematic Evaluation of Patients Treated With Neurothrombectomy Devices for Acute Ischemic Stroke), which prospectively enrolled patients treated in the United States with a Solitaire Revascularization Device and Mindframe Capture Low Profile Revascularization Device within 8 hours from symptom onset, was compared with the interventional cohort from the patient-level meta-analysis from Campbell et al., to assess whether similar process timelines and technical and functional outcomes could be achieved in a large real world cohort as in the randomized trials. The conclusion of the article was that the results indicate that randomized trials can be reproduced in the real-world (Mueller-Kronast et al., 2017).[110]

The applicant stated that based on these data, U.S. clinical guidelines now recommend mechanical thrombectomy for the treatment of large vessel occlusion strokes when performed ≤6 hours from symptom onset. The American Stroke Association/American Heart Association (ASA/AHA) ''2018 Guidelines for the Early Management of Patients With Acute Ischemic Stroke'' recommends mechanical thrombectomy with a stent retriever in patients that meet the following criteria: (1) Prestroke modified Rankin Scale (mRS) 0–1, (2) causative occlusion of the internal carotid artery (ICA) or middle cerebral artery (MCA) segment 1 (M1), (3) age ≥18, (4) National Institute of Health Stroke Scale (NIHSS) ≥6, (5) Alberta Stroke Program Early CT Score (ASPECTS) ≥6, and (6) treatment can be initiated within 6 h of symptom onset (Powers et al., 2018). The ASA/AHA notes the need for expeditious treatment with both intravenous thrombolysis and mechanical thrombectomy.[111]

The applicant also stated that recently, randomized trials have demonstrated the clinical efficacy of mechanical thrombectomy for large vessel occlusion strokes for select patients from 6 to 24 hours after symptom onset.[112] Among patients with acute stroke who were last known well 6 to 24 hours earlier and who had a mismatch between clinical deficit and infarct, outcomes for disability at 90 days were better with thrombectomy plus standard care compared with standard care alone.

The applicant asserted that the use of ContaCT reduces time to treatment, by notifying the stroke team faster than the standard of care and enabling the team to diagnose and treat the patient earlier, which is known to improve clinical outcomes in stroke, and that mechanical thrombectomy has been shown to reduce disability, reduce length of stay and recovery time (Campbell, BCV et al. 2017).[113]

According to the applicant, other studies have also demonstrated that time to reperfusion is a predictor of patient outcomes. The applicant asserted that several major randomized controlled trials for mechanical thrombectomy have demonstrated improvements in functionality with faster time to reperfusion. The primary outcome of some of these trials was the modified Rankin scale (mRs) score, a categorical scale measure of functional outcome, with scores ranging from 0 (no symptoms) to 6 (death) at 90 days.[114] Pooled patient-level data from these five trials demonstrated that in the mechanical thrombectomy group the odds of better disability outcomes at 90

[107] U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. Evaluation of Automatic Class III Designation for ContaCT. Decision Memorandum No. 170073 (DEN170073). 2018. Retrieved from: *https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170073.pdf.*

[108] Berkhemer OA, Fransen PS, Beumer D, et al. MR CLEAN Investigators. A randomized trial of intraarterial treatment for acute ischemic stroke. *N Engl J Med.* 2015;372:11–20.doi: 10.1056/NEJMoa1411587; Campbell BCV, Mitchell PJ, Kleinig TJ, et al. Endovascular therapy for ischemic stroke with perfusion-imaging selection. *N Engl J Med.* 2015;372(11):1009–1018; Jovin TG, Chamorro A, Cobo E, de Miquel MA, Molina CA, Rovira A, et al.; REVASCAT Trial Investigators. Thrombectomy within 8 hours after symptom onset in ischemic stroke. *N Engl J Med.* 2015;372(24):2296–2306.

[109] Campbell BC, Hill MD, Rubiera M et al. Safety and efficacy of solitaire stent thrombectomy: Individual patient data meta-analysis of randomized trials. *Stroke.* 2016;47(3):798–806; Goyal M, Menon BK, van Zwam WH, et al. Endovascular thrombectomy after large-vessel ischaemic stroke: A meta-analysis of individual patient data from five randomised trials. *Lancet N Am Ed.* 2016;387(10029):1723–1731.

[110] Mueller-Kronast NH, Zaidat OO, Froehler MT, et al. Systematic evaluation of patients treated with neurothrombectomy devices for acute ischemic stroke: Primary results of the STRATIS registry. *Stroke.* 2017;48(10):2760–2768.

[111] Powers WJ, Rabinstein AA, Ackerson T et al. On behalf of the American Heart Association Stroke Council. 2018 Guidelines for the early management of patients with acute ischemic stroke: A guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke.* 2018;49:e46–e110.

[112] Albers GW, Marks MP, Kemp S, et al. Thrombectomy for stroke at 6 to 16 hours with selection by perfusion imaging. *N Engl J Med.* 2018;378(8):708–718; Nogueira RG, Jadhav AP, Haussen DC, et al. Thrombectomy 6 to 24 hours after stroke with a mismatch between deficit and infarct. *N Engl J Med.* 2018;378(1):11–21.

[113] Campbell BCV, Mitchell PJ, Churilov L, et al. Endovascular Thrombectomy for Ischemic Stroke Increases Disability-Free Survival, Quality of Life, and Life Expectancy and Reduces Cost. *Front Neurol.* 2017;8:657.

[114] Berkhemer OA, Fransen PS, Beumer D, et al. MR CLEAN Investigators. A randomized trial of intraarterial treatment for acute ischemic stroke. *N Engl J Med.* 2015;372:11–20.doi: 10.1056/NEJMoa1411587; Campbell BCV, Mitchell PJ, Kleinig TJ, et al. Endovascular therapy for ischemic stroke with perfusion-imaging selection. *N Engl J Med.* 2015;372(11):1009–1018; Goyal M, Demchuk AM, Menon BK, Eesa M, Rempel JL, Thornton J, et al.; ESCAPE Trial Investigators. Randomized assessment of rapid endovascular treatment of ischemic stroke. *N Engl J* Med. 2015;372(11):1019–1030; Jovin TG, Chamorro A, Cobo E, de Miquel MA, Molina CA, Rovira A, et al.; REVASCAT Trial Investigators. Thrombectomy within 8 hours after symptom onset in ischemic stroke. N Engl J Med. 2015;372(24):2296–2306; Saver JL, Goyal M, Bonafe A, Diener HC, Levy EI, Pereira VM, et al.; SWIFT PRIME Investigators. Stent-retriever thrombectomy after intravenous t-PA vs. t-PA alone in stroke. N Engl J Med. 2015 Jun 11;372(24):2285–95.

days (mRS scale distribution) declined with longer time from symptom onset to expected arterial puncture. Among the mechanical thrombectomy plus medical therapy group patients in whom substantial reperfusion was achieved, delays in reperfusion times were associated with increased levels of 3-month disability.[115]

The applicant referred to the American Stroke Association/American Heart Association (ASA/AHA) ''2018 Guidelines for the Early Management of Patients With Acute Ischemic Stroke,'' which recognize that the benefit of mechanical thrombectomy is time dependent, with earlier treatment within the therapeutic window leading to bigger proportional benefits. The guidelines also state that any cause for delay to mechanical thrombectomy, including observing for a clinical response after IV alteplase, should be avoided.[116]

The applicant asserted that the phrase ''time is brain'' emphasizes that human nervous tissue is rapidly lost as stroke progresses. Per the applicant, recent advances in quantitative neurostereology and stroke neuroimaging permit calculation of just how much brain is lost per unit time in acute ischemic stroke. To illustrate this point, the applicant stated that in the event of a large vessel acute ischemic stroke, the typical patient loses 1.9 million neurons, 13.8 billion synapses, and 12 km (7 miles) or axonal fibers each minute in which stroke is untreated. Furthermore, for each hour in which treatment fails to occur, the brain loses as many neurons as it does in almost 3.6 years of normal aging.[117] The applicant asserted that given the time-dependent nature of treatment in acute ischemic stroke patients, ContaCT could play a critical role in preserving human nervous tissue, as the application results in faster detection in more than 95% of cases and saves an average of 51.4 minutes in time to notification.[118]

We have the following concerns regarding whether the technology meets the substantial clinical improvement criterion. The applicant provided a total of 19 articles specifically for the purposes of addressing the substantial clinical improvement criterion: Four retrospective studies/analyses, nine randomized clinical trials (RCTs), three meta-analyses, one registry, one guideline, and one systematic review.

The four retrospective studies/analyses included the FDA decision memorandum, a single site of a RCT, and two abstracts related to the Automated Large Artery Occlusion Detection in Stroke Imaging (ALADIN) study. The applicant stated that the studies sponsored/conducted by the De Novo requester indicated that ContaCT substantially shortens the time to notifying the specialist for LVO cases as compared with the standard of care. However, the sample size was limited to only 85 out of 300 patients having sufficient data of CTA to notification time available. To calculate the sensitivity and specificity of ContaCT, neuro-radiologists reviewed images and established the empirical evidence. Specifically, the sensitivity and specificity was 87.8% (95% CI 81.2–92.5%) and 89.6% (83.7–93.9%) respectively. We have concerns regarding whether this represents a substantial clinical improvement, as ContaCT missed approximately 12% of images with a true LVO and incorrectly identified approximately 10% as having a LVO. Additionally, the small sample size of less than 100 raises concerns for generalizability. Additionally, we agree with FDA that ContaCT is limited to analysis of imaging data and should not be used in-lieu of full patient evaluation or relied upon to make or confirm diagnosis.[119]

With respect to the study that was a single site of a RCT [120] presented by the applicant, the study conducted a retrospective review of the time between an initial CT at an outside hospital and the notification to the comprehensive stroke center. This retrospective analysis was conducted at one site, enrolled in one of the RCTs (unspecified). The authors noted there was substantial difference in the time between initial CT at the outside hospital to comprehensive stroke center notification, due to multiple factors, including delays in neurological assessments, interpretation of imaging, utilization of advance modality imaging, and determination of tPA effectiveness. Specifically, the authors noted in their study that obtainment of advanced imaging contributed to a 57-minute delay in decision making without substantial benefits in patient outcome. It is unclear whether and how this time delay and the utilization of faster notification would affect the clinical outcome of patients.

The applicant also submitted two separate abstracts for a retrospective analysis of the ALADIN study, which only provide interim results. The applicant noted for the primary analysis, the algorithm obtained sensitivity of 0.97 and specificity of 0.52, with a positive predictive value (PPV) of 0.74 and negative predictive NPV of 0.91, and overall accuracy of 0.78. For the secondary analysis (M2 and proximal ICA included), the algorithm obtained sensitivity of 0.92 and specificity of 0.75, with a PPV of 0.92 and NPV of 0.75, and overall accuracy of 0.88. We are concerned both that these are only partial results as it is not clear what the full outcome of the ALADIN study will indicate, and also that the initial overall accuracy of ContaCT varied by 10% between the types of strokes.

The RCTs included the following: (1) Multicenter Randomized Clinical Trial of Endovascular Treatment of Acute Ischemic Stroke in the Netherlands (MR CLEAN), (2) Thrombolysis in Emergency Neurological Deficits—Intra-Arterial (EXTEND–IA) Trial, (3) The Endovascular Treatment for Small Core and Anterior Circulation Proximal Occlusion with Emphasis on Minimizing CT to Recanalization Times (ESCAPE) trial, (4) Randomized Trial of Revascularization with Solitaire FR Device versus Best Medical Therapy in the Treatment of Acute Stroke Due to Anterior Circulation Large Vessel Occlusion Presenting within Eight Hours of Symptom Onset (REVASCAT), (5) Solitaire with the Intention for Thrombectomy as Primary Endocascular Treatment (SWIFT PRIME) trial, (6) Endovascular Therapy Following Imaging Evaluation for Ischemic Stroke, (7) DWI or CTP Assessment with Clinical Mismatch in the Triage of Wake-Up and Late Presenting Strokes Undergoing Neurointervention with Trevo (DAWN) trial, and (8) Interventional Manage of Stroke (IMS) Phase I and II trials. The MR CLEAN trial, EXTEND–IA trial, ESCAPE trial,

[115] Saver JL, Goyal M, van der Lugt A, et al.; HERMES Collaborators. Time to treatment with endovascular thrombectomy and outcomes from ischemic stroke: A meta-analysis. *JAMA.* 2016;316:1279–1288.

[116] Powers WJ, Rabinstein AA, Ackerson T et al. On behalf of the American Heart Association Stroke Council. 2018 Guidelines for the early management of patients with acute ischemic stroke: A guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke.* 2018;49:e46–e110.

[117] Saver JL. Time is brain—quantified. *Stroke.* 2006 Jan;37(1):263–6.

[118] U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. Evaluation of Automatic Class III Designation for ContaCT. Decision Memorandum No. 170073 (DEN170073). 2018. Retrieved from: *https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170073.pdf.*

[119] U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. Evaluation of Automatic Class III Designation for ContaCT. Decision Memorandum No. 170073 (DEN170073). 2018. Retrieved from: *https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170073.pdf.*

[120] Sun CH, Nogueira J, Glenn RG, et al. Picture-to-puncture: A novel time metric to enhance outcomes in patients transferred for endovascular reperfusion in acute ischemic stroke. *Circulation.* 2013;127:1139–1148.

REVASCAT trial, SWIFT PRIME trial, Endovascular Therapy Following Imaging Evaluation for Ischemic Stroke trial, and DAWN were all multi-center prospective RCTs evaluating a treatment group of either a microcatheter with a thrombolytic agent or mechanical thrombectomy versus a control group of the standard care. These RCTs were evaluating the outcomes from specific treatment for patients who suffered from various strokes and not the time of imaging to treatment. While each study may have included a time-element as an experimental analysis or additional end-point, we are unsure how they support the use of ContaCT as a substantial clinical improvement over existing technologies. Also, while the IMS trials provided evidence to support a positive clinical outcome following technically successful angiographic reperfusion using time from stroke onset to procedure termination, they did not specify which part of the overall standard of care treatment affected an increase or decrease of time. The three meta-analyses utilized data from the RCTs. The Safety and Efficacy of Solitaire Stent Thrombectomy examined four trials, ESCAPE, REVASCAT, SWIFT PRIME, and EXTEND–IA. The Highly Effective Reperfusion evaluated in Multiple Endovascular Stroke Trials (HERMES) collaboration authored two of the three meta-analysis. The HERMES collaboration examined data and results from five RCTs, MR CLEAN, ESCAPE, REVASCAT, SWIFT PRIME, and EXTEND–IA. These meta-analysis studies confirmed the results of each of the individual RCTs of the benefits of thrombectomy versus the standard of care. However, we have concerns as to whether these meta-analyses, along with the RCTs, indicate a substantial clinical improvement with shorter notification times of a LVO.

Two articles submitted by the applicant evaluated data using the STRATIS registry. One article [121] evaluated the use of mechanical thrombectomy in consecutive patients with acute ischemic stroke because of LVO in the anterior circulation. The two groups consisted of (1) patients who presented directly to a comprehensive stroke center and (2) patients who were transferred to a comprehensive stroke center. This study identified a difference of 124 minutes between groups, which was primarily related to longer door-to-tPA times at nonenrolling hospitals, delay between IV-tPA and departure from the initial hospital, and length of transport time. The author's primary outcome was functional status at 90 days, which found those with shorter time to treatment achieved better functional independence at 90 days. There was no difference in mortality in the two groups. While this article supports that shorter time to treatment may increase positive clinical outcomes for functional status, the study indicated time to departure from the nonenrolling hospital and transfer time as primary reasons in delayed thrombectomy treatment. These two time lapses include multiple covariates; for example, the distance between the facilities and the response of available transport (for example, ambulance). These potential confounders raise questions as to the use of ContaCT shortening time to treatment.

Lastly, the applicant submitted the AHA/ASA guidelines and a systematic literature review as support for clinical improvement. We are concerned the guidelines do not support a finding of substantial clinical improvement for ContaCT because the guidelines are for current standard of care. The systematic literature review identified the quantitative estimates of the pace of neural circuity loss in human ischemic stroke. While this supports the urgency of stroke care, we are unsure how it demonstrates a substantial clinical improvement in how ContaCT supports the urgency of stroke care.

We invite public comment as to whether ContaCT meets the substantial clinical improvement criterion.

In this section, we summarize and respond to written public comments received in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for ContaCT.

Comment: Several commenters asserted that the studies conducted to date specifically demonstrate the important relationship between time to treatment and improved clinical outcomes in ischemic stroke. The commenters emphasized the concept of ''time is brain,'' that human nervous tissue is rapidly lost as stroke progresses and emergent evaluation and therapy are required. They stated that in patients experiencing a typical large vessel acute ischemic stroke, 120 million neurons, 830 billion synapses, and 714 km (447 miles) of myelinated fibers are lost each hour, and that 1.9 million neurons, 14 billion synapses, and 12 km (7.5 miles) of myelinated fibers are destroyed every minute. The commenters noted that, compared with the normal rate of neuron loss in brain aging, the ischemic brain ages 3.6 years each hour without treatment. They also re-emphasized the time dependency of stroke interventions, stating that the sooner the reperfusion therapy is commenced, the better the outcome. A commenter stated that, following implementation of ContaCT in May 2019, CTA time at stroke center (PSC) to time of arrival at comprehensive stroke center (CSC) was significantly reduced by an average of 66 min. (mean CTA to time of arrival, 171.29 ± 110.58 min. vs 105.27 ± 62.09 min; $p = 0.0163$). Another commenter stated that, following implementation of ContaCT in January 2019, the spoke door-in to groin puncture at CSC was reduced by 26.0 min (14%) while also reducing the standard deviation by 25.0 min (38%). (Median CTA to time of groin puncture, 188.5 ± 65.5 min. vs 162.5 ± 40.5 min). Commenters stated that although sample sizes are currently too small to identify meaningful differences in clinical outcomes, the incorporation of ContaCT was associated with a significant improvement in transfer times for LVO patients and that given what is known about the importance of decreasing time to treatment, time savings achieved should result in better outcomes.

Response: We thank the commenters for their input and will take this information into consideration when deciding whether to approve new technology add-on payments for ContaCT.

Comment: The applicant responded to the questions received at the New Technology Town Hall Meeting held in December 2019.

First, the applicant was asked how the time prior to emergency department (ED) arrival affects the benefit of reduced time-to-notification from ContaCT and whether the benefit from the algorithm would reach a limit such that there would still be loss of brain function due to delays prior to ED arrival. The applicant responded that there is a large body of clinical evidence showing that delay in treatment (thrombectomy) in patients with stroke with large vessel occlusion leads to poorer outcomes and that time from symptoms to treatment may be broken down into 3 discrete windows: (1) Initiation of symptoms to arrival of emergency medical services (EMS), (2) EMS arrival at the patient's location to transport to an emergency department, and (3) arrival at an emergency department to start of treatment (''door to puncture''). They further stated that interventions to reduce the times in each of these windows independently can help improve patient outcomes. The

[121] Froehler MT, Saver JL, Zaidat 00, et al. Interhospital transfer before thrombectomy is associated with delayed treatment and worse outcome in the STRATIS registry. *Circulation.* 2017; 136(24):2311–2321.

applicant stated that the ContaCT system is designed to optimize processes inside the hospital but acknowledged that process changes that reduce the time interval between EMS arrival and enrolling hospital arrival may further benefit patients with acute ischemic stroke, but the opportunity to improve processes outside the hospital does not reduce or limit the benefit of reducing time to treatment by improving processes inside the hospital through use of the ContaCT system.

Second, the applicant was asked how the algorithm driving ContaCT is maintained. The applicant responded that changes to the algorithm code are controlled via a software development life-cycle procedure (SDLC) that is designed to comply with FDA requirements and IEC62304 (Medical device software—Software life cycle processes). The applicant stated that the procedure includes a regulatory evaluation, performed according to relevant FDA guidance and that the manufacturer maintains the performance of the ContaCT device using user feedback where issues and complaints are logged, tracked and investigated according to the manufacturer's quality management system (QMS), designed in compliance with relevant FDA regulations (21 CFR part 820) and inspected on a quarterly basis during management review. Also, medical annotators routinely review scans, and an analysis of sensitivity and specificity (overall and per institution) is reviewed by management during the quarterly management review. Criteria for acceptance of said performance are predefined in the QMS.

Third, the applicant was asked if the results for ContaCT are only generalizable to those centers where mechanical thrombectomy is performed or whether ContaCT works only in specialized stroke centers. The applicant stated that the benefits of this parallel workflow are not limited to tertiary stroke centers and that conclusions from the STRATIS Registry suggest there is an opportunity to optimize processes both inside and outside the hospital.

Lastly, the applicant was asked if there is clinical evidence demonstrating that ContaCT directly improves clinical outcomes. The applicant acknowledged that there is no data directly evaluating patient outcomes from ContaCT but stated that there is evidence from randomized controlled trials and real world studies of reduction in time from ED presentation to notification for treatment of LVO. The applicant also noted that there is a large and well-established body of evidence that reduced time to notification and treatment of LVO improves patient outcomes in patients with ischemic stroke. Per the applicant, this body of evidence supports the conclusion that ContaCT provides substantial clinical improvement over current standard of care in Medicare beneficiaries with acute ischemic stroke.

Response: We appreciate the applicant's responses to questions asked at the New Technology Town Hall Meeting. We will take the responses to our questions into consideration when deciding whether to approve new technology add-on payments for ContaCT.

d. Supersaturated Oxygen (SSO_2) Therapy (DownStream® System)

TherOx, Inc. submitted an application for new technology add-on payments for Supersaturated Oxygen (SSO_2) Therapy (the TherOx DownStream® System) for FY 2021. We note that the applicant previously submitted an application for new technology add-on payments for FY 2019, which was withdrawn prior to the issuance of the FY 2019 IPPS/LTCH PPS final rule. We also note that the applicant again submitted an application for new technology add-on payments for FY 2020, but CMS was unable to determine that SSO_2 Therapy represents a substantial clinical improvement over the currently available therapies used to treat STEMI patients.

Per the applicant, The DownStream® System is an adjunctive therapy that creates and delivers superoxygenated arterial blood directly to reperfused areas of myocardial tissue which may be at risk after an acute myocardial infarction (AMI), or heart attack. Per FDA, SSO_2 Therapy is indicated for the preparation and delivery of SuperSaturated Oxygen Therapy (SSO_2 Therapy) to targeted ischemic regions perfused by the patient's left anterior descending coronary artery immediately following revascularization by means of percutaneous coronary intervention (PCI) with stenting that has been completed within 6 hours after the onset of anterior acute myocardial infarction (AMI) symptoms caused by a left anterior descending artery infarct lesion. The applicant stated that the net effect of the SSO_2 Therapy is to reduce the size of the infarction and, therefore, lower the risk of heart failure and mortality, as well as improve quality of life for STEMI patients.

SSO_2 Therapy consists of three main components: the DownStream® System; the DownStream cartridge; and the SSO_2 delivery catheter. The DownStream® System and cartridge function together to create an oxygen-enriched saline solution called SSO_2 solution from hospital-supplied oxygen and physiologic saline. A small amount of the patient's blood is then mixed with the SSO_2 solution, producing oxygen-enriched hyperoxemic blood, which is delivered to the left main coronary artery (LMCA) via the delivery catheter at a flow rate of 100 ml/min. The duration of the SSO_2 Therapy is 60 minutes and the infusion is performed in the catheterization laboratory. The oxygen partial pressure (pO_2) of the infusion is elevated to ~1,000 mmHg, therefore providing oxygen locally to the myocardium at a hyperbaric level for 1 hour. After the 60-minute SSO_2 infusion is complete, the cartridge is unhooked from the patient and discarded per standard practice. Coronary angiography is performed as a final step before removing the delivery catheter and transferring the patient to the intensive care unit (ICU).

The applicant for the SSO_2 Therapy received conditional premarket approval from FDA on April 2, 2019. FDA noted the applicant must conduct ''a post-approval study to confirm the safety and effectiveness of the TherOx DownStream System for use of delivery of SuperSaturated Oxygen Therapy (SSO_2 Therapy) to targeted ischemic regions of the patient's coronary vasculature in qualifying anterior acute myocardial infarction (AMI) patients who have undergone successful percutaneous coronary intervention (PCI) with stenting within 6 hours of experiencing AMI symptoms.'' [122] The applicant stated that use of the SSO_2 Therapy can be identified by the ICD–10–PCS procedure codes 5A0512C (Extracorporeal supersaturated oxygenation, intermittent) and 5A0522C (Extracorporeal supersaturated oxygenation, continuous).

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would therefore not be considered ''new'' for purposes of new technology add-on payments. We note that in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42275), we stated that based on the information submitted by the applicant as part of its FY 2020 new technology add-on payment application for SSO_2 Therapy, as discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19353), and as summarized in the FY 2020 IPPS/LTCH PPS final rule, we believe that SSO_2 Therapy has a unique mechanism

[122] *https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170027A.pdf.*

of action as it delivers a localized hyperbaric oxygen equivalent to the coronary arteries immediately after administering the standard-of-care, PCI with stenting, in order to restart metabolic processes within the stunned myocardium and reduce infarct size. Therefore, we stated that we believe SSO_2 Therapy is not substantially similar to existing technologies and meets the newness criterion. We also stated that we would consider the beginning of the newness period to commence when SSO_2 Therapy was approved by the FDA on April 2, 2019. We refer the reader to the FY 2020 final rule for the complete discussion of how SSO_2 Therapy meets the newness criterion. We welcome any additional information or comments in response to this proposed rule regarding whether SSO_2 Therapy is substantially similar to an existing technology and whether it meets the newness criterion for purposes of its application for new technology add-on payments for FY 2021.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that SSO_2 Therapy meets the cost criterion. The applicant searched the FY 2018 MedPAR file for claims reporting diagnoses of anterior STEMI by ICD–10–CM diagnosis codes I21.01 (ST elevation (STEMI) myocardial infarction involving left main coronary artery), I21.02 (ST elevation (STEMI) myocardial infarction involving left anterior descending coronary artery), or I21.09 (ST elevation (STEMI) myocardial infarction involving other coronary artery of anterior wall) as a principal diagnosis, which the applicant believed would describe potential cases representing potential patients who may be eligible for treatment involving the SSO_2 Therapy. The applicant identified 9,111 cases mapping to 4 MS–DRGs, with approximately 95 percent of all potential cases mapping to MS–DRG 246 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+ Arteries/Stents) and MS–DRG 247 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent without MCC). The remaining 5 percent of potential cases mapped to MS–DRG 248 (Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent with MCC or 4+ Arteries/Stents) and MS–DRG 249 (Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent without MCC).

The applicant determined that the average case-weighted unstandardized charge per case was $97,049. The applicant then standardized the charges. The applicant did not remove charges for the current treatment because, as previously discussed, SSO_2 Therapy would be used as an adjunctive treatment option following successful PCI with stent placement. The applicant then added charges for the technology, which accounts for the use of 1 cartridge per patient, to the average charges per case. The applicant did not apply an inflation factor to the charges for the technology. The applicant also added charges related to the technology, to account for the additional supplies used in the administration of SSO_2 Therapy, as well as 70 minutes of procedure room time, including technician labor and additional blood tests. The applicant inflated the charges related to the technology. In the applicant's analysis, the inflated average case-weighted standardized charge per case was $150,115 and the average case-weighted threshold amount was $98,332. Because the inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

We invite public comments on whether the SSO_2 Therapy meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that SSO_2 Therapy represents a substantial clinical improvement over existing technologies because it improves clinical outcomes for STEMI patients as compared to the currently available standard-of-care treatment, PCI with stenting alone. Specifically, the applicant asserted that: (1) Infarct size reduction improves mortality outcomes; (2) infarct size reduction improves heart failure outcomes; (3) SSO_2 Therapy significantly reduces infarct size; (4) SSO_2 Therapy prevents left ventricular dilation; and (5) SSO_2 Therapy reduces death and heart failure at 1 year. The applicant highlighted the importance of the SSO_2 Therapy's mechanism of action, which treats hypoxemic damage at the microvascular or microcirculatory level. Specifically, the applicant noted that microvascular impairment in the myocardium is irreversible and leads to a greater extent of infarction. According to the applicant, the totality of the data on myocardial infarct size, ventricular remodeling, and clinical outcomes strongly supports the substantial clinical benefit of SSO_2 Therapy administration over the standard-of-care.

As stated above, TherOx, Inc. submitted an application for new technology add-on payments for FY 2020 that was denied on the basis of substantial clinical improvement. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42278), we stated that we were not approving new technology add-on payments for SSO_2 Therapy for FY 2020 because, after consideration of the comments received, we remained concerned that the current data did not adequately support a sufficient association between the outcome measures of heart failure, rehospitalization, and mortality with the use of SSO_2 Therapy specifically to determine that the technology represents a substantial clinical improvement over existing available options. The applicant resubmitted its application for new technology add-on payments for FY 2021 with new information that, per the applicant, demonstrates that there is an unmet medical need for STEMI, and that SSO_2 Therapy provides a treatment option for a patient population unresponsive to currently available treatments. Below we summarize the studies the applicant submitted with both its FY 2020 and FY 2021 applications, followed by the new information the applicant submitted with its FY 2021 application to support that the technology is represents a substantial clinical improvement.

In the FY 2020 application, as summarized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42275), and the FY 2021 application, the applicant cited an analysis of the Collaborative Organization for RheothRx Evaluation (CORE) trial and a pooled patient-level analysis to support the claims that infarct size reduction improves mortality and heart failure outcomes.

- The CORE trial was a prospective, randomized, double-blinded, placebo-controlled trial of Poloxamer 188, a novel therapy adjunctive to thrombolysis at the time the study was conducted.[123] The applicant sought to relate left ventricular ejection fraction (EF), end-systolic volume index (ESVI) and infarct size (IS), as measured in a single, randomized trial, to 6-month mortality after myocardial infarction treated with thrombolysis. According to the applicant, subsets of clinical centers participating in CORE also participated in one or two radionuclide sub-studies: (1) Angiography for measurement of EF and absolute, count-based LV volumes; and (2) single-photon emission computed tomographic sestamibi measurements of IS. These sub-studies were performed in 1,194 and 1,181 patients, respectively, of the 2,948

[123] Burns, R.J., Gibbons, R.J., Yi, Q., et al., ''The relationships of left ventricular ejection fraction, end-systolic volume index and infarct size to six-month mortality after hospital discharge following myocardial infarction treated by thrombolysis,'' *J Am Coll Cardiol,* 2002, vol. 39, pp. 30–6.

patients enrolled in the trial. Furthermore, ejection fraction, ESVI, and IS, as measured by central laboratories in these sub-studies, were tested for their association with 6-month mortality. According to the applicant, the results of the study showed that ejection fraction (n=1,137; p=0.0001), ESVI (n=945; p=0.055) and IS (n=1,164; p=0.03) were all associated with 6-month mortality, therefore, demonstrating the relationship between these endpoints and mortality.[124]

- The pooled patient-level analysis was performed from 10 randomized, controlled trials (with a total of 2,632 patients) that used primary PCI with stenting.[125] The analysis assessed infarct size within 1 month after randomization by either cardiac magnetic resonance (CMR) imaging or technetium-99m sestamibi single-photon emission computed tomography (SPECT), with clinical follow-up for 6 months. Infarct size was assessed by CMR in 1,889 patients (71.8 percent of patients) and by SPECT in 743 patients (28.2 percent of patients) including both inferior wall and more severe anterior wall STEMI patients. According to the applicant, median infarct size (or percent of left ventricular myocardial mass) was 17.9 percent and median duration of clinical follow-up was 352 days. The Kaplan-Meier estimated 1-year rates of all-cause mortality, re-infarction, and HF hospitalization were 2.2 percent, 2.5 percent, and 2.6 percent, respectively. The applicant noted that a strong graded response was present between infarct size (per 5 percent increase) and the 2 outcome measures of subsequent mortality (Cox-adjusted hazard ratio: 1.19 [95 percent confidence interval: 1.18 to 1.20]; p<0.0001) and hospitalization for heart failure (adjusted hazard ratio: 1.20 [95 percent confidence interval: 1.19 to 1.21]; p<0.0001), independent of other baseline factors.[126] The applicant concluded from this study that infarct size, as measured by CMR or technetium-99m sestamibi SPECT within 1 month after primary PCI, is strongly associated with all-cause mortality and hospitalization for heart failure within 1 year.

In the FY 2020 application, the applicant also cited the AMIHOT I and II studies to support the claim that SSO_2 Therapy significantly reduces infarct size.

- The AMIHOT I clinical trial was designed as a prospective, randomized evaluation of patients who had been diagnosed with AMI, including both anterior and inferior patients, and received treatment with either PCI with stenting alone or with SSO_2 Therapy as an adjunct to successful PCI within 24 hours of symptom onset.[127] The study included 269 randomized patients and 3 co-primary endpoints: Infarction size reduction, regional wall motion score improvement at 3 months, and reduction in ST segment elevation. The study was designed to demonstrate superiority of the SSO_2 Therapy group as compared to the control group for each of these endpoints, as well as to demonstrate non-inferiority of the SSO_2 Therapy group with respect to 30-day Major Adverse Cardiac Event (MACE). The applicant stated that results for the control versus SSO_2 Therapy group comparisons for the three co-primary effectiveness endpoints demonstrated a nominal improvement in the test group, although this nominal improvement did not achieve clinical and statistical significance in the entire population. The applicant further stated that a pre-specified analysis of the SSO_2 Therapy patients who were revascularized within 6 hours of AMI symptom onset and who had anterior wall infarction showed a marked improvement in all 3 co-primary endpoints as compared to the control group.[128] Key safety data revealed no statistically significant differences in the composite primary endpoint of 1-month (30 days) MACE rates between the SSO_2 Therapy and control groups. MACE includes the combined incidence of death, re-infarction, target vessel revascularization, and stroke. In total, 9/134 (6.7 percent) of the patients in the SSO_2 Therapy group and 7/135 (5.2 percent) of the patients in the control group experienced 30-day MACE (p=0.62).[129]
- The AMIHOT II trial randomized 301 patients who had been diagnosed with and receiving treatment for anterior AMI with either PCI plus the SSO_2 Therapy or PCI alone.[130] The AMIHOT II trial had a Bayesian statistical design that allows for the informed borrowing of data from the previously completed AMIHOT I trial. The primary efficacy endpoint of the study required proving superiority of the infarct size reduction, as assessed by Tc-99m Sestamibi SPECT imaging at 14 days post PCI/stenting, with the use of SSO_2 Therapy as compared to patients who were receiving treatment involving PCI with stenting alone. The primary safety endpoint for the AMIHOT II trial required a determination of non-inferiority in the 30-day MACE rate, comparing the SSO_2 Therapy group with the control group, within a safety delta of 6.0 percent.[131] Endpoint evaluation was performed using a Bayesian hierarchical model that evaluated the AMIHOT II result conditionally in consideration of the AMIHOT I 30-day MACE data. According to the applicant, the results of the AMIHOT II trial showed that the use of SSO_2 therapy, together with PCI and stenting, demonstrated a relative reduction of 26 percent in the left ventricular infarct size and absolute reduction of 6.5 percent compared to PCI and stenting alone.[132]

Next, to support the claim that SSO_2 Therapy prevents left ventricular dilation, the applicant cited the Leiden study, which represents a single-center, sub-study of AMIHOT I patients treated at Leiden University in the Netherlands. The study describes outcomes of randomized selective treatment with intracoronary aqueous oxygen (AO), the therapy delivered by SSO_2 Therapy, versus standard care in patients who had acute anterior wall myocardial infarction within 6 hours of onset. Of the 50 patients in the sub-study, 24 received treatment using adjunctive AO and 26 were treated according to standard care after PCI, with no significant differences in baseline characteristics between groups. LV volumes and function were assessed by contrast echocardiography at baseline and 1 month. According to the applicant, the results demonstrated that treatment with aqueous oxygen prevents LV remodeling, showing a reduction in LV volumes (3 percent decrease in LV end-diastolic volume and 11 percent decrease in LV end-systolic volume) at 1 month as compared to baseline in AO-treated patients, as compared to increasing LV volumes (14 percent increase in LV end diastolic volume and 18 percent increase in LV end-systolic volume) at 1 month in control patients.[133] The results also show that

[124] Ibid.

[125] Stone, G.W., Selker, H.P., Thiele, H., et al., ''Relationship between infarct size and outcomes following primary PCI,'' *J Am Coll Cardiol,* 2016, vol. 67(14), pp. 1674–83.

[126] Ibid.

[127] O'Neill, W.W., Martin, J.L., Dixon, S.R., et al., ''Acute Myocardial Infarction with Hyperoxemic Therapy (AMIHOT), *J Am Coll Cardiol,* 2007, vol. 50(5), pp. 397–405.

[128] Ibid.

[129] Ibid.

[130] Stone, G.W., Martin, J.L., de Boer, M.J., et al., ''Effect of Supersaturated Oxygen Delivery on Infarct Size after Percutaneous Coronary Intervention in Acute Myocardial Infarction,'' *Circ Cardiovasc Intervent,* 2009, vol. 2, pp. 366–75.

[131] Ibid.

[132] Ibid.

[133] Warda, H.M., Bax, J.J., Bosch, J.G., et al., ''Effect of intracoronary aqueous oxygen on left ventricular remodeling after anterior wall ST-

treatment using AO preserves LV ejection fraction at 1 month, with AO-treated patients experiencing a 10 percent increase in LV ejection fraction as compared to a 2 percent decrease in LV ejection fraction among patients in the control group.[134]

Finally, to support the claim that SSO_2 Therapy reduces death and heart failure at 1 year, the applicant submitted the results from the IC– HOT clinical trial, which was designed to confirm the safety and efficacy of the use of the SSO_2 Therapy in those individuals presenting with a diagnosis of anterior AMI, who have undergone successful PCI with stenting of the proximal and/or mid left anterior descending artery within 6 hours of experiencing AMI symptoms. It is an IDE, nonrandomized, single arm study. The study primarily focused on safety, utilizing a composite endpoint of 30-day Net Adverse Clinical Events (NACE). A maximum observed event rate of 10.7 percent was established based on a contemporary PCI trial of comparable patients who had been diagnosed with anterior wall STEMI. The results of the IC–HOT trial exhibited a 7.1 percent observed NACE rate, meeting the study endpoint. Notably, no 30-day mortalities were observed, and the type and frequency of 30-day adverse events occurred at similar or lower rates than in contemporary STEMI studies of PCI-treated patients who had been diagnosed with anterior AMI.[135] Furthermore, according to the applicant, the results of the IC–HOT study supported the conclusions of effectiveness established in AMIHOT II with a measured 30-day median infarct size = 19.4 percent (as compared to the AMIHOT II SSO_2 Therapy group infarct size = 20.0 percent).[136] The applicant stated that notable measures include 4-day microvascular obstruction (MVO), which has been shown to be an independent predictor of outcomes, 4-day and 30-day left ventricular end diastolic and end systolic volumes, and 30-day infarct size.[137] The applicant also stated that the IC–HOT study results exhibited a favorable MVO as compared to contemporary trial data, and decreasing left ventricular volumes at 30 days, compared to contemporary PCI populations that exhibit increasing left ventricular size.[138] The applicant asserted that the IC–HOT clinical trial data continue to demonstrate the substantial clinical benefit of the use of SSO_2 Therapy as compared to the standard-of-care, PCI with stenting alone.

The applicant also performed controlled studies in both porcine and canine AMI models to determine the safety, effectiveness, and mechanism of action of the SSO_2 Therapy.[139] [140] According to the applicant, the key summary points from these animal studies are:

- SSO_2 Therapy administration post-AMI acutely improves heart function as measured by left ventricular ejection fraction (LVEF) and regional wall motion as compared with non-treated control subjects.
- SSO_2 Therapy administration post-AMI results in tissue salvage, as determined by post-sacrifice histological measurements of the infarct size. Control animals exhibit larger infarcts than the SSO_2-treated animals.
- SSO_2 Therapy has been shown to be non-toxic to the coronary arteries, myocardium, and end organs in randomized, controlled swine studies with or without induced acute myocardial infarction.
- SSO_2 Therapy administration post-AMI has exhibited regional myocardial blood flow improvement in treated animals as compared to controls.
- A significant reduction in myeloperoxidase (MPO) levels in the SSO_2-treated animals versus controls, which indicate improvement in underlying myocardial hypoxia.
- Transmission electron microscopy (TEM) photographs showing amelioration of endothelial cell edema and restoration of capillary patency in ischemic zone cross-sectional histological examination of the SSO_2-treated animals, while non-treated controls exhibit significant edema and vessel constriction at the microvascular level.

In the FY 2020 final rule (84 FR 42278), after consideration of all the information from the applicant, as well as the public comments we received, we stated that we were unable to determine that SSO_2 Therapy represented a substantial clinical improvement over the currently available therapies used to treat STEMI patients. We stated that we remained concerned that the current data does not adequately support a sufficient association between the outcome measures of heart failure, rehospitalization, and mortality with the use of SSO_2 Therapy specifically to determine that the technology represented a substantial clinical improvement over existing available options. Therefore, we did not approve new technology add-on payments for SSO_2 Therapy for FY 2020.

For FY 2021, the applicant submitted new information that, according to the applicant, demonstrates that there is an unmet medical need for STEMI, and that SSO_2 Therapy provides a treatment option for a patient population unresponsive to currently available treatments. The applicant presented this information in the context of CMS's concerns as identified in the FY 2020 IPPS/LTCH PPS proposed and final rules, specifically that (1) it is unclear whether use of the SSO_2 Therapy would demonstrate the same clinical improvement as compared to the current standard of care; (2) that the current data does not adequately support a sufficient association between the outcome measures of heart failure, rehospitalization, and mortality with the use of SSO_2 Therapy, and (3) that SSO_2 may not provide long-term clinical benefits in patients with AMI. Below we summarize this information, which the applicant believes addresses these concerns.

With regard to CMS's concern that it is unclear whether use of SSO_2 Therapy would demonstrate the same clinical improvement as compared to the current standard-of care, the applicant restated our concern as whether ''these data [AMIHOT I and AMIHOT II are] adequate to show the relevant outcomes in the control (standard of care percutaneous coronary intervention (PCI)''. In response to this concern, the applicant asserted that patient outcomes post-PCI have remained relatively stable over the past 10 years and there is a strong clinical need for new therapies like SSO_2 in addition to PCI in the management of patients with anterior STEMI to reduce the risk and severity of heart failure and death. To support its assertion of an unmet clinical need for anterior wall STEMI treatment, the applicant presented data from multiple references to illustrate the following:

- A plateauing in STEMI 1-year mortality rates at 10 percent with the advent of drug-eluting stents, according to reports from the SWEDEHEART registry. This statistic is in agreement with the 9% 1year STEMI mortality rate

elevation acute myocardial infarction,'' *Am J Cardiol,* 2005, vol. 96(1), pp. 22–4.

[134] Ibid.

[135] David, SW, Khan, Z.A., Patel, N.C., et al., ''Evaluation of intracoronary hyperoxemic oxygen therapy in acute anterior myocardial infarction: The IC–HOT study,'' *Catheter Cardiovasc Interv,* 2018, pp. 1–9.

[136] Ibid.

[137] Ibid.

[138] Ibid.

[139] Spears, J.R., Henney, C., Prcevski, P., et al., ''Aqueous Oxygen Hyperbaric Reperfusion in a Porcine Model of Myocardial Infarction,'' *J Invasive Cardiol,* 2002, vol. 14(4), pp. 160–6.

[140] Spears, J.R., Prcevski, P., Xu, R., et al., ''Aqueous Oxygen Attenuation of Reperfusion Microvascular Ischemia in a Canine Model of Myocardial Infarction,'' *ASAIO J,* 2003, vol. 49(6), pp. 716–20.

following PCI reported in a 2015 paper by Bullock et al.[141]

- No improvement in U.S. in-hospital post-PCI STEMI mortality rates between 2001 and 2011 based on work done by Sugiyama et al.[142]
- No decrease in one-year mortality risk as illustrated by Kalesan et al.,[143] a meta-analysis of 15 clinical trials totaling 7,867 patients that compared outcomes data for STEMI patients treated with bare metal stents versus drug eluting stents.[144]
- A markedly higher one-year mortality rate at 19.4% for the Medicare population as compared to the total population of PCI-treated anterior wall STEMI patients, according to the most recent Medicare Standard Analytic File (SAF) data (2017).
- No improvement in congestive heart failure (CHF) rates after STEMI treated pPCI; the applicant referenced Szummer et al.'s [145] work which indicated 1 year post primary PCI CHF rates of 10 percent as well as a statistical analysis of CHF readmission outcomes that showed heart failure rates for this patient population have remained stable at 9 to 10 percent from 2012 to 2017.
- A decrease in 30-day STEMI re-hospitalizations due to the evolution of PCI therapy; the applicant cited the work of Kim et al.,[146] noting the readmission rates trended slightly downward from approximately 12 percent in 2010 to 10 percent in 2014. According to the applicant, these data illustrate that PCI treats macrovascular aspects of STEMI events, but does not address the underlying infarct damage, which is highly correlated with worse long-term outcomes.

The applicant reiterated statements from its prior application that, in order to reduce outcomes like mortality and heart failure in the STEMI population, therapies must be available above and beyond PCI to reduce the size of the infarct that results from a STEMI event. Per the applicant, the benefits shown in the AMIHOT I 6-hour sub-study, AMIHOT II and IC–HOT studies show statistically significant and clinically meaningful improvements in infarct size, left ventricular size and function, and long term outcomes that support the claim that SSO_2 offers a substantial clinical improvement over PCI by filling an important gap in therapy with PCI, and specifically the need to reduce infarct size beyond simply opening occluded large vessels alone.

With regard to CMS's second concern that the current data does not adequately support a sufficient association between the outcome measures of heart failure, rehospitalization, and mortality with the use of SSO_2 Therapy, the applicant restated our concern as ''the importance of the reduction of infarct size as an outcome for patients with anterior STEMI.'' The applicant provided multiple animal and human studies to illustrate how TherOx SSO_2 potentially impacts outcome measures of heart failure, rehospitalization and mortality. Regarding animal studies, the applicant cited the porcine and canine study by Spears et al. and summarized above to illustrate how aqueous oxygen hyperoxemic perfusion attenuates microvascular ischemia.[147] [148] Regarding human studies, the applicant cited a 2004 review by Gibbons et al. to support its assertion that the best physical measure of the consequences of AMI in post-intervention patients is the quantification of the extent of necrosis or infarction in the muscle. In this 2004 review article, Gibbons et al. sought to summarize published evidence for quantification of infarct size using data from studies that assessed biomarkers, cardiac SPECT sestamibi and magnetic resonance imaging.[149] Regarding the use of cardiac SPECT sestamibi imaging, Gibbons et al. found five separate lines of clinical evidence that validated the use of SPECT sestamibi imaging for determining infarct size.[150] The applicant also referenced the CORE trial that it submitted with its original application and which we summarize above. Per the applicant, a substudy of CORE trial data by Burns et al. demonstrated that an absolute infarct size reduction of 3 percent was associated with a mortality benefit.[151] Specifically, the trial showed that six-month mortality was significantly related to infarct size. Per the applicant, among the 753 patients who underwent ejection fraction measurements, the odds ratio for infarct size for six-month mortality was 1.033—that is, for each 1 percent increase in infarct size, mortality in the next 6 months was 1.033 times more likely. A 5 percent increase in infarct size would therefore mean that 6-month mortality was 1.176 times more likely. A patient with an infarct size that was greater by 5 percent of the left ventricle would therefore have a 17.6 percent greater chance of dying within the next 6 months.[152]

The applicant further noted the CORE trial and associated studies were conducted when thrombolytic therapy was the standard of care for coronary artery reperfusion. The transition to PCI led directly to a measured absolute infarct size reduction of 5.1 percent in STEMI patients treated with PCI as compared to thrombolytic therapy, which correlated to a significant decrease in cardiovascular events. The applicant asserted that the infarct size reduction demonstrated with PCI compared to thrombolytic therapy helped establish PCI as the preferred standard of care, and that the results demonstrating the importance of infarct size reduction hold true in randomized PCI trials of STEMI patients, with infarct size evaluated by either Tc-99 sestabmibi SPECT imaging or cardiac MRI. The applicant referred to the substudy of CORE trial data by Burns et al., which found that, among the three clinical prognostic outcomes studied, ejection fraction (EF) was superior to infarct size (IS) and end-systolic volume index (ESVI) in predicting 6-month mortality.[153] The authors also noted that all three radionuclide measures were significantly associated with each other, and that the strongest correlation was between ESVI and EF. The study noted that infarct size was significantly correlated with both EF and ESVI despite being determined from a different radionuclide measurement,

[141] Bulluck H, Yellon DM, and Hausenloy DJ. Reducing myocardial infarct size: Challenges and future opportunities. Heart 2016;102:341–48.

[142] Sugiyama T, Hasegawa K, Kobayashi Y, Takahashi O, Fukui T, Tsugawa Y. Differential time trends of outcomes and costs of care for acute myocardial infarction hospitalizations by ST elevation and type of intervention in the United States, 2001–2011. J AmHeart Assoc. 2015;4:e001445. doi:10.1161/JAHA.114.001445

[143] Kalesan B, Pilgrim T, Heinimann K, et al. Comparison of drug-eluting stents with bare metal stents in patients with ST-segment elevation myocardial infarction. Eur Heart J 2012;33:977–87.

[144] Id.

[145] Szummer K, Wallentin L, Lindhagen L, et al. Improved outcomes in patients with ST-elevation myocardial infarction during the last 20 years are related to implementation of evidence-based treatments: Experiences from the SWEDEHEART registry 1995–2014. Eur Heart J 2017;38:3056–65.

[146] Kim LK, Yeo I, Cheung, JW, et al. Thirty-Day Readmission Rates, Timing, Causes, and Costs after ST-Segment Myocardial Infarction in the United States: A National Readmission Database Analysis 2010–2014. J Am Heart Assoc 2018;7(18):1–34.

[147] Spears JR, Henney C, Prcevski P, et al. Aqueous Oxygen Hyperbaric Reperfusion in a Porcine Model of Myocardial Infarction. *J Invasive Cardiol* 2002; 14(4):160–6.

[148] Spears JR, Prcevski P, Xu R, et al. Aqueous Oxygen Attenuation of Reperfusion Microvascular Ischemia in a Canine Model of Myocardial Infarction. *ASAIO J* 2003; 49(6):716–20.

[149] Gibbons RJ, Valeti US, Araoz PA, et al. The quantification of infarct size. *J Am Coll Cardiol* 2004; 44:1533–42.

[150] Id.

[151] Burns RJ, Gibbons RJ, Yi Q, et al. The relationships of left ventricular ejection fraction, end-systolic volume index and infarct size to six-month mortality after hospital discharge following myocardial infarction treated by thrombolysis. *J Am Coll Cardiol* 2002; 39:30–6.

[152] Id.

[153] Id.

and that infarct location was not found to be significant.[154]

The applicant also provided a study by Stone et al.[155] to address our concern that the current data does not adequately support a sufficient association between the outcome measures of heart failure, rehospitalization, and mortality with the use of SSO_2 Therapy. The applicant provided Stone et al.'s recent analysis of 10 pooled randomized trials involving 2,632 subjects, including some subjects from the AMIHOT II trial. Stone et al. set out to determine the strength of the relationship between infarct size assessed within 1 month after pPCI in STEMI and subsequent all-cause mortality, reinfarction and hospitalization for heart failure.[156] Infarct size was assessed using cardiac SPECT sestamibi or cardiac magnetic resonance and clinical follow-up data greater than or equal to 6 months. The authors found infarct size reduction measured by either imaging method within 1 month correlated strongly with reduced mortality and heart failure hospitalization at 1 year. The applicant asserted that the results demonstrated that every 5 percent absolute increase in left ventricular infarct size was associated with a 19 percent increase in 1-year mortality, correlating well with the 17.6 percent estimate established from earlier data and underscoring the important, independent relationship between infarct size and mortality regardless of the treatment modality. The applicant asserted that the published analysis also demonstrated that infarct size measured within 1 month after pPCI for STEMI using either imaging method is a powerful independent predictor of hospitalization for heart failure at 1 year. The applicant reiterated that overall, a 5 percent absolute infarct size increase was associated with a 20 percent increase in either death or heart failure at 1 year. The applicant explained that because infarct size is the quantification of the extent of scarring of the left ventricle post-AMI, it is a direct measure of the health of the myocardium and indirectly of the heart's structure and function. A large infarct means the muscle cannot contract normally, leading to left ventricular enlargement, reduced ejection fraction, clinical heart failure, and death. Per the applicant, the Kaplan-Meier curves for the rates of heart failure at 12 months as a function of infarct size also show that a 5 percent increase in left ventricle infarct size corresponded to a 50–100 percent increase in the risk of heart failure at 12 months for the most severe infarcts. The applicant concluded that reducing infarct size 5 or more percentage points provides a clear and dramatic clinical benefit for patients as demonstrated by a wealth of trial data. Significantly, the applicant noted that even as treatment of the primary occlusion improved, the relationship between infarct size and mortality and heart failure persisted and remained present throughout the study data.

Finally, with regard to CMS's third concern that SSO_2 may not provide long-term clinical benefits in patients with AMI, the applicant again referred to the 1-year outcomes data collected from patients in the IC–HOT trial and which were compared to a control population from the INFUSE AMI study after propensity-matching. The applicant asserted that STEMI patients treated with SSO_2 Therapy showed statistically significant and clinically meaningful improvements in several critically important outcomes for patients with anterior STEMI at 1 year, such as—

- Death;
- New onset of heart failure and readmission for heart failure;
- Composite rate of death and new onset of heart failure;
- Composite rate of death, new onset of heart failure or readmission for heart failure, or clinically-driven target vessel revascularization;
- Composite of death, reinfarction/spontaneous MI, clinically driven target vessel revascularization or new onset heart failure or readmission for heart failure.

The applicant concluded that, taken together, there is abundant evidence to support the claim that SSO_2 Therapy represents a substantial clinical improvement over PCI alone in the management of patients with anterior STEMI. Per the applicant, there remains a strong unmet need for new therapies like SSO_2 in addition to PCI in the management of patients with anterior STEMI to reduce the risk and severity of heart failure and death. The applicant maintained that the timely delivery of supersaturated oxygen therapy improves microvascular and tissue level flow, reduces infarct size, facilitates recovery of left ventricular function and preserves left ventricular stability, and improves patient outcomes, most notably lowering mortality and heart failure rates at 1 year post-procedure.

We thank the applicant for the additional information to address the concerns discussed in the FY 2020 IPPS/LTCH PPS final rule. We appreciate how this information, and specifically the seven studies referenced in response to the applicant's restatement of our first concern, illustrates a potential unmet medical need. However, we are concerned that the AMIHOT I and AMIHOT II data may not adequately demonstrate the relevant outcomes in the control (standard of care PCI) because the standard of care has evolved since the two trials were performed. Additionally, we are concerned that the results presented in these seven studies may be based on patients with all types of STEMI and are not specific to the FDA-approved indicated use of SSO_2 Therapy for the treatment of anterior STEMI. Ultimately, we remain concerned that the current data does not support a sufficient association between the outcome measures of heart failure, rehospitalization, and mortality with the use of SSO_2 Therapy specifically to determine that the technology represents a substantial clinical improvement over existing available options. Therefore, we are inviting public comment on whether SSO_2 meets the substantial clinical improvement criterion.

We are inviting public comments on whether the SSO_2 Therapy meets the substantial clinical improvement criterion.

In this section we summarize and respond to written public comments we received in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for SSO_2 Therapy.

Comment: Several commenters were supportive of the new technology add-on payment application for SSO_2 Therapy. These comments were primarily in response to CMS's previous concerns about whether SSO_2 Therapy satisfied the substantial clinical improvement criterion. The commenters noted that there is still an unmet need for additional therapies for large anterior STEMIs in patients over the age of 65 years. A commenter emphasized that the evolution in STEMI care since the advent of stenting was in the improvement of stent materials and the organization of medical care, including reducing time from symptom onset to first medical contact, door to balloon time, total ischemic time, and improving antithrombotic therapy, but that these efforts all occur before the therapeutic intervention, which has remained unchanged since the advent of drug-eluting stents. Another commenter

[154] Id.

[155] Stone GW, Selker, HP, Thiele H, et al. Relationship between infarct size and outcomes following primary PCI. JACC 2016;67(14):1674–83.

[156] Id.

noted that improvements in short-term mortality in STEMI are largely due to the adoption of reperfusion therapy, and in particular percutaneous coronary angioplasty (PCI) with stenting. The commenter asserted that while more widespread adoption of this standard of care has been vital in reducing hospital readmission rates, the mortality and incidence of heart failure for STEMI patients treated with PCI have not improved since the AMIHOT II study was conducted. The commenter concluded that there remains a significant unmet need for additional therapies to address reperfusion injury, microvascular damage, and infarct size, especially in the case of large anterior STEMIs in patients over the age of 65 years, where current data show that patients treated with PCI demonstrate a 1-year mortality of nearly 20 percent and an incidence of heart failure over 10 percent.

Another commenter asserted that SSO_2 was shown to be safe and effective and did not increase the already known early complications associated with an acute myocardial infarction combined with acute coronary intervention. The commenters supported the applicant's assertion that SSO_2 Therapy reduced infarct size, which is a surrogate for improved clinical outcomes. A commenter noted that the 6.5 percent reduction in infarct size achieved with SSO_2 Therapy in AMIHOT trials has major clinical relevance and is further confirmed by the results of the IC–HOT study, where SSO_2 therapy was associated with superior one-year clinical outcomes compared with the current standard of care with PCI alone. This commenter noted that IC–HOT patients also demonstrated favorable effects on ventricular remodeling consistent with findings in the AMIHOT trials, and also demonstrated favorable effects for microvascular obstruction, which the commenter asserted is an additional independent predictor of outcomes. This commenter referenced the meta-analysis by Stone et al. that showed reducing infarction size led to reduced mortality, improved long-term clinical outcomes, improved quality of life, and reduced heart failure and related medical expenses.[157]

Response: We appreciate the information provided by the commenters. We will take these comments into consideration when deciding whether to approve new technology add-on payments for SSO_2 Therapy for FY 2021.

[157] Stone GW, Selker, HP, Thiele H, et al. Relationship between infarct size and outcomes following primary PCI. JACC 2016;67(14):1674–83.

e. Eluvia™ Drug-Eluting Vascular Stent System (Eluvia)

Boston Scientific submitted an application for new technology add-on payments for the Eluvia™ Drug-Eluting Vascular Stent System for FY 2021. Eluvia™, a drug-eluting stent for the treatment of lesions in the femoropopliteal arteries, received FDA premarket approval (PMA) September 18, 2018. The applicant asserts that Eluvia™ was first commercially available on the market on October 4, 2018 and the first procedure with Eluvia™ following FDA approval in the U.S. occurred on October 5, 2018. We note that the applicant submitted an application for new technology add-on payments for FY 2020. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42231), we stated that we remain concerned that we do not have enough information to determine that the Eluvia™ device represents a substantial clinical improvement over existing technologies. Therefore, we did not approve the Eluvia™ device for FY 2020 new technology add-on payments. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42220 through 42231) for a complete discussion regarding the Eluvia™ device's FY 2020 new technology application.

According to the applicant, the Eluvia™ system is a sustained release drug-eluting stent indicated for the treatment of lesions in the femoropopliteal arteries and is designed to restore blood flow in the peripheral arteries above the knee—specifically the superficial femoral artery (SFA) and proximal popliteal artery (PPA). The applicant asserts that this device/drug combination product for endovascular treatment of peripheral artery disease (PAD) utilizes a polymer that carries and protects the drug before and during the procedure and ensures that the drug is released into the tissue in a controlled, sustained manner to prevent the restenosis of the vessel. The applicant further asserts that Eluvia™ system's stent platform is purpose-built to address the mechanical challenges of the SFA with an optimal amount of strength, flexibility and fracture resistance. According to the applicant, Eluvia™'s polymer-based drug delivery system is uniquely designed to sustain the release of paclitaxel beyond 1year to match the restenotic process in the SFA. The Eluvia™ system is indicated for improving luminal diameter in the treatment of symptomatic de-novo or restenotic lesions in the native SFA and/or PPA with reference vessel diameters (RVD) ranging from 4.0 to 6.0 mm and total lesion lengths up to 190mm, according to the applicant.

The applicant asserts that the Eluvia™ system is comprised of the implantable endoprosthesis and the stent delivery system. The stent is a laser cut self-expanding stent composed of a nickel titanium alloy (nitinol). On both the proximal and distal ends of the stent, radiopaque markers made of tantalum increase visibility of the stent to aid in placement. The triaxial designed delivery system consists of 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 (0.89 mm) guidewires. The Eluvia™ stent is available in a variety of diameters and lengths. The delivery system is offered in two working lengths including 75 and 130 cm.

Peripheral artery disease (PAD) is a circulatory problem in which narrowed arteries reduce blood flow to the limbs, usually in the legs. Symptoms of PAD may include lower extremity pain due to varying degrees of ischemia and claudication, which is characterized by pain induced by exercise and relieved with rest. Risk factors for PAD include age ≥70 years; age 50 to 69 years with a history of smoking or diabetes; age 40 to 49 with diabetes and at least one other risk factor for atherosclerosis; leg symptoms suggestive of claudication with exertion, or ischemic pain at rest; abnormal lower extremity pulse examination; known atherosclerosis at other sites (for example, coronary, carotid, renal artery disease); smoking; hypertension, hyperlipidemia, and homocysteinemia.[158] PAD is primarily caused by atherosclerosis—the buildup of fatty plaque in the arteries. PAD can occur in any blood vessel, but it is more common in the legs than the arms. Approximately 8.5 million people in the United States have PAD, including 12–20% of individuals older than age 60.[159]

A diagnosis of PAD is established with the measurement of an ankle-brachial index (ABI) ≤0.9. The ABI is a comparison of the resting systolic blood pressure at the ankle to the higher systolic brachial pressure. Duplex ultrasonography is commonly used in conjunction with the ABI to identify the

[158] Neschis, David G. & MD, Golden, M. (2018). Clinical features and diagnosis of lower extremity peripheral artery disease. Retrieved October 29, 2018, from *https://www.uptodate.com/contents/clinical-features-and-diagnosis-of-lower-extremity-peripheral-artery-disease.*

[159] Centers for Disease Control and Prevention. (2018). Peripheral Arterial Disease (PAD) Fact Sheet. Retrieved from *https://www.cdc.gov/DHDSP/data_statistics/fact_sheets/fs_PAD.htm.*

location and severity of arterial obstruction.[160]

Management of disease is aimed at improving symptoms, improving functional capacity, and preventing amputations and death. Management of patients with lower extremity PAD may include medical therapies to reduce the risk for future cardiovascular events related to atherosclerosis, such as myocardial infarction, stroke, and peripheral arterial thrombosis. Such therapies may include antiplatelet therapy, smoking cessation, lipid-lowering therapy, and treatment of diabetes and hypertension. For patients with significant or disabling symptoms unresponsive to lifestyle adjustment and pharmacologic therapy, intervention (percutaneous, surgical) may be needed. Surgical intervention includes angioplasty, a procedure in which a balloon-tip catheter is inserted into the artery and inflated to dilate the narrowed artery lumen. The balloon is then deflated and removed with the catheter. For patients with limb-threatening ischemia (for example pain while at rest and or ulceration), revascularization is a priority to reestablish arterial blood flow. According to the applicant, treatment of the SFA is problematic due to multiple issues, including high rate of restenosis and significant forces of compression.

[160] Berger, J. & Davies, M. (2018). Overview of lower extremity peripheral artery disease. Retrieved October 29, 2018 from *https://www.uptodate.com/contents/overview-of-lower-extremity-peripheral-artery-disease.*

The applicant asserts that the Eluvia™ Drug-Eluting Vascular Stent System is a sustained-release drug-eluting self-expanding, nickel titanium alloy (nitinol) mesh stent used to reestablish blood flow to stenotic arteries. According to the applicant, the Eluvia™ system is the first stent specifically designed for deployment in the SFA and/or PPA that utilizes the anti-restenotic drug paclitaxel in conjunction with a polymer. Eluvia™ is built on the Innova™ Stent System platform, consisting of a self-expanding nitinol stent and an advanced, 6F low-profile triaxial delivery system for added support and placement accuracy. The Eluvia™ stent is coated with the drug paclitaxel, which helps prevent the artery from restenosis. The Eluvia™ Stent System is comprised of the implantable endoprosthesis and the stent delivery system (SDS).

According to the applicant, there are four principal treatment options for PAD, including two endovascular approaches (angioplasty and stenting):

- Medical therapy, typically for those with mild to medium symptoms. This may include pharmacotherapy (for example, cilostazil) and exercise therapy.
- Angioplasty, a procedure in which a catheter with a balloon on the tip is inserted into an artery and inflated to expand the artery and reduce the blockage. The balloon is then deflated and removed with the catheter. Some procedures use drug coated balloons, in which a drug is applied to the lesion at the time of balloon inflation.
- Stenting via a procedure in which a stent is placed in the artery to keep the artery open and prevent it from re-narrowing. This can be done with a bare metal stent or with a drug-eluting stent, which also releases a drug that helps slow the re-narrowing of the vessel.
- For patients with severe narrowing that is blocking blood flow, bypass surgery may be warranted. In the procedure, a healthy vein is used to make a new path around the narrowed or blocked artery.

The applicant further asserts that aside from Eluvia™, the alternative existing endovascular approaches (angioplasty and stenting) do not provide a sustained release application of a drug and that Eluvia™ is the first polymer-based, drug-eluting stent designed to treat and restore blood flow in the peripheral arteries above the knee, and the eluted medication helps to prevent tissue regrowth during the entire period most commonly associated with restenosis. According to the applicant, the sustained release of the anti-restenotic drug is intentionally designed to elute over a 12–15-month period delivering the drug when restenosis is most likely to occur, which the applicant states is a significantly longer period than the two-month duration of drug eluted from drug-coated balloons and the paclitaxel-coated Zilver PTX drug eluting stent.

The Eluvia™ stent system was granted approval for the following ICD–10–PCS procedure codes effective October 1, 2019:

ICD-10-PCS Code	Code Description
X27H385	Dilation of Right Femoral Artery with Sustained Release Drug-eluting Intraluminal Device, Percutaneous Approach, New Technology Group 5
X27H395	Dilation of Right Femoral Artery with Two Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5
X27H3B5	Dilation of Right Femoral Artery with Three Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5
X27H3C5	Dilation of Right Femoral Artery with Four or More Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5
X27J385	Dilation of Left Femoral Artery with Sustained Release Drug-eluting Intraluminal Device, Percutaneous Approach, New Technology Group 5
X27J395	Dilation of Left Femoral Artery with Two Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5
X27J3B5	Dilation of Left Femoral Artery with Three Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5
X27J3C5	Dilation of Left Femoral Artery with Four or More Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5
X27K385	Dilation of Proximal Right Popliteal Artery with Sustained Release Drug-eluting Intraluminal Device, Percutaneous Approach, New Technology Group 5
X27K395	Dilation of Proximal Right Popliteal Artery with Two Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5
X27K3B5	Dilation of Proximal Right Popliteal Artery with Three Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5
X27K3C5	Dilation of Proximal Right Popliteal Artery with Four or More Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5
X27L385	Dilation of Proximal Left Popliteal Artery with Sustained Release Drug-eluting Intraluminal Device, Percutaneous Approach, New Technology Group 5
X27L395	Dilation of Proximal Left Popliteal Artery with Two Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5
X27L3B5	Dilation of Proximal Left Popliteal Artery with Three Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5
X27L3C5	Dilation of Proximal Left Popliteal Artery with Four or More Sustained Release Drug-eluting Intraluminal Devices, Percutaneous Approach, New Technology Group 5

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would therefore not be considered ''new'' for purposes of new technology add-on payments. We note that in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42227), we stated that after consideration of the applicant's comments, we believe that the Eluvia™ device uses a unique mechanism of action to achieve a therapeutic outcome when compared to existing technologies such as the paclitaxel-coated stent. Therefore, we stated that the Eluvia™ device meets the newness criterion. We refer the reader to the FY 2020 final rule for the complete discussion of how the Eluvia™ device meets the newness criterion. The applicant noted in its FY 2021 application that for FY 2020, CMS concluded that the Eluvia™ device met the newness criterion. The applicant stated that it believes there is no basis for CMS to reach a contrary conclusion with regard to whether the Eluvia™ system meets the newness criterion for FY 2021. The applicant also reiterated that the Eluvia™ device uses a unique mechanism of action because it utilizes a sustained-release of a low-dose of paclitaxel. We welcome any additional information or comments in response to this proposed rule regarding whether the Eluvia™ device is substantially similar to an existing technology and whether it meets the newness criterion for purposes of its application for new technology add-on payments for FY 2021.

With regard to the cost criterion, the applicant conducted two analyses based on 100 percent of identified claims and 76 percent of identified claims. To identify potential cases where Eluvia™ could be utilized, the applicant searched the FY 2018 MedPAR file for ICD–10–PCS codes from the Peripheral Drug Eluting Stent and Peripheral Bare Metal Stent categories. For the analysis using 100 percent of cases, the applicant identified a total of 11,051 cases spanning 150 MS–DRGs. The applicant then removed charges for the technology being replaced. The applicant stated that because it was unable to determine a more specific percentage reduction, it chose the most conservative approach for calculation purposes and removed 100% of charges associated with service category Medical/Surgical Supply Charge Amount, which included revenue center 027x. The applicant then standardized the charges and applied an inflation factor of 11.1%, which is the same inflation factor used by CMS to update the outlier threshold in the FY 2020 IPPS/LTCH PPS final rule, to update the charges from FY 2018 to FY 2020 (84 FR 42629). The applicant added charges for the new technology by multiplying the cost of the technology by the national CCR for implantable devices (0.299) from the FY 2020 IPPS final rule. Under the analysis based on 100% of identified claims, the applicant determined an average case-

weighted threshold amount of $100,851 and a final average inflated standardized charge per case of $157,343.

Under the analysis based on 76 percent of identified claims, the applicant used the same methodology, which identified 8,335 cases across 8 MS–DRGs. The applicant determined the average case-weighted threshold amount of $98,196 and a final inflated average standardized charge per case of $147,343. Because the final inflated average standardized charge per case exceeded the case-weighted threshold amount under both analyses, the applicant asserted that the technology meets the cost criterion. We invite public comments on whether Eluvia™ meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserts that Eluvia™ represents a substantial clinical improvement over existing technologies because it achieves superior primary patency; reduces the rate of subsequent therapeutic interventions; decreases the number of future hospitalizations or physician visits; reduces hospital readmission rates; reduces the rate of device related complications; and achieves similar functional outcomes and EQ–5D index values while associated with half the rate of TLRs.

As stated above, Boston Scientific submitted an application for new technology add-on payments for the Eluvia™ device for FY 2020 that was not approved. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42231), we noted the FDA's preliminary review of data that identified a potentially concerning signal of increased long-term mortality in study subjects treated with paclitaxel-coated products compared to patients treated with uncoated devices, and stated that we remained concerned that we did not have enough information to determine that the Eluvia™ device represents a substantial clinical improvement over existing technologies. The applicant resubmitted its application for new technology add-on payments for FY 2021 with updated two-year primary patency results to demonstrate that the Eluvia™ device represents a substantial clinical improvement over existing technologies. Below we summarize the studies the applicant submitted with both its FY 2020 and FY 2021 applications, followed by the new information the applicant submitted with its FY 2021 application to support that the technology represents a substantial clinical improvement.

The applicant submitted the results of the MAJESTIC study, a single-arm first-in-human study of Eluvia™. The MAJESTIC [161] study is a prospective, multicenter single-arm, open label study. Per the applicant, the MAJESTIC study demonstrated long-term treatment durability among patients whose femoropopliteal arteries were treated with the Eluvia™ stent. The MAJESTIC study enrolled 57 patients with symptomatic lower limb ischemia and lesions in the superficial femoral artery or proximal popliteal artery. Efficacy measures at 2 years included primary patency, defined as duplex ultrasound peak systolic velocity ratio of <2.5 and the absence of target lesion revascularization (TLR) or bypass. Safety monitoring through 3 years included adverse events and TLR. The 24-month clinic visit was completed by 53 patients; 52 had Doppler ultrasound evaluable by the core laboratory, and 48 patients had radiographs taken for stent fracture analysis. The 3-year follow-up was completed by 54 patients. At 2 years, 90.6% (48/53) of patients had improved by one or more Rutherford categories as compared with the pre-procedure level without the need for TLR (when those with TLR were included, 96.2% sustained improvement); only one patient exhibited a worsening in level, 66.0% (35/53) of patients exhibited no symptoms (category 0) and 24.5% (13/53) had mild claudication (category 1) at the 24-month visit. Mean ABI improved from 0.73 ± 0.22 at baseline to 1.02 ± 0.20 at 12 months and 0.93 ± 0.26 at 24 months. At 24 months, 79.2% (38/48) of patients had an ABI increase of at least 0.1 compared with baseline or had reached an ABI of at least 0.9. According to the applicant, the primary patency rate at 12 months was 96.4%. With regard to the Eluvia™ stent achieving superior primary patency, the applicant submitted the results of the IMPERIAL [162] trial in which the Eluvia™ stent is compared, head-to-head, to the Zilver® PTX® drug-eluting stent. The IMPERIAL study is a global, multi-center, randomized controlled trial consisting of 465 subjects. Eligible patients were aged 18 years or older and had symptomatic lower-limb ischaemia, defined as Rutherford category 2, 3, or 4 and stenotic, restenotic (treated with a drug-coated balloon >12 months before the study or standard percutaneous transluminal angioplasty only), or occlusive lesions in the native superficial femoral artery or proximal popliteal artery, with at least one infrapopliteal vessel patent to the ankle or foot. Patients had to have stenosis of 70% or more (via angiographic assessment), vessel diameter between 4 mm and 6 mm, and total lesion length between 30 mm and 140 mm.

Subjects who had previously stented target lesion/vessels treated with drug-coated balloon <12 months prior to randomization/enrollment and subjects who had undergone prior surgery of the SFA/PPA in the target limb to treat atherosclerotic disease were excluded from the study. Two concurrent single-group (Eluvia™ only) sub studies were done: A non-blinded, non-randomized pharmacokinetic sub study and a non-blinded, non-randomized study of patients with long lesions (>140 mm). The IMPERIAL study is a prospective, multicenter, single-blinded randomized, controlled (RCT) non-inferiority trial. Patients were randomized (2:1) to implantation of either a paclitaxel-eluting polymer stent (Eluvia™) or a paclitaxel-coated stent (Zilver® PTX®) after the treating physician had successfully crossed the target lesion with a guide wire. The primary endpoints of the study are Major Adverse Events defined as all causes of death through 1 month, Target Limb Major Amputation through 12 months and/or Target Lesion Revascularization (TLR) through 12 months, and primary vessel patency at 12 months post-procedure. Secondary endpoints included the Rutherford categorization, Walking Impairment Questionnaire, and EQ- 5D assessments at 1 month and 6 months post-procedure. Patient demographic and characteristics were balanced between Eluvia™ stent and Zilver® PTX® stent groups.

The applicant noted that lesion characteristics for the Eluvia™ stent vs Zilver® PTX® stent arms were comparable. Clinical follow-up visits related to the study were scheduled for 1 month, 6 months, and 12 months after the procedure, with follow-up planned to continue through 5 years, including clinical visits at 24 months and 5 years and clinical or telephone follow-up at 3 and 4 years.

The applicant asserts that in the IMPERIAL study, the Eluvia™ stent demonstrated superior primary patency over the Zilver® PTX® stent, with 86.8% vs. 77.5% respectively (p=0.0144). The non-inferiority primary efficacy endpoint was also met. The applicant asserts that the SFA presents unique challenges with respect to maintaining long-term patency. There are distinct

[161] Müller-Hülsbeck S et al. Long-Term Results from the MAJESTIC Trial of the Eluvia Paclitaxel-Eluting Stent for Femoropopliteal Treatment: 3-Year Follow-up. Cardiovasc Intervent Radiol. 2017 Dec;40(12):1832–1838.

[162] 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 Sep 24.

pathological differences between the SFA and coronary arteries. The SFA tends to have higher levels of calcification and chronic total occlusions when compared to coronary arteries. Following an intervention within the SFA, the SFA produces a healing response which often results in restenosis or re-narrowing of the arterial lumen. This cascade of events leading to restenosis starts with inflammation, followed by smooth muscle cell proliferation and matrix formation.[163] Because of the unique mechanical forces in the SFA, this restenotic process of the SFA can continue well beyond 300 days from the initial intervention. Primary patency at 12 months, by Kaplan-Meier estimate, was significantly greater for Eluvia™ than for Zilver® PTX®, with 88.5% and 79.5% respectively (p=0.0119). According to the applicant, these results are consistent with the 96.4% primary patency rate at 12 months in the MAJESTIC study, the single-arm first-in-human study of Eluvia™.

The IMPERIAL study included two concurrent single-group (Eluvia™ only) sub studies: A non-blinded, non-randomized pharmacokinetic sub study and a non-blinded, non-randomized study of patients with long lesions (>140 mm). For the pharmacokinetic sub study, patients had venous blood drawn before stent implantation, at intervals ranging from 10 minutes to 24 hours post implantation, and then at either 48 hours or 72 hours post implantation. The pharmacokinetics sub study confirmed that plasma paclitaxel concentrations after Eluvia™ implantation were well below thresholds associated with toxic effects in studies in patients with cancer (0·05 μM or ~43 ng/mL).

The IMPERIAL sub study long lesion subgroup consisted of 50 patients with average lesion length of 162.8 mm that were each treated with two Eluvia™ stents. Twelve-month outcomes for the long lesion subgroup are 87% primary patency and 6.5% Target Lesion Revascularization (TLR). In a subgroup analysis of patients 65 years and older (Medicare population), the primary patency rate in the Eluvia™ stent group is 92.6%, compared to 75.0% for the Zilver® PTX® stent group (p=0.0386).

With regard to reducing the rate of subsequent therapeutic interventions, secondary outcomes in the IMPERIAL study included repeat re-intervention on the same lesion, target lesion revascularization (TLR). The rate of subsequent interventions, or TLRs, in the Eluvia™ stent group was 4.5% compared to 9.0% in the Zilver® PTX® stent group. The applicant asserts that TLR rate in the Eluvia™ group represents a substantial reduction in re-intervention on the target lesion compared to that of the Zilver® PTX® stent group.

With regard to decreasing the number of future hospitalizations or physician visits, the applicant asserts that the substantial reduction in the lesion revascularization rate led to a reduced need to provide additional intensive care, distinguishing the Eluvia™ group from the Zilver® PTX® group. In the IMPERIAL study, Eluvia™-treated patients required fewer days of re-hospitalization. There were 13.9 post procedure in-hospital days in the Eluvia™ group for all adverse events compared to 17.7 post procedure in-hospital days in the Zilver® PTX® group. There were 2.8 post procedure in-hospital days in the Eluvia™ group for TLR/Total Vessel Revascularization (TVR) compared to 7.1 post procedure in-hospital days in the Zilver® PTX® group. And lastly, there were 2.7 post-procedure in-hospital days from the Eluvia™ group for procedure/device related adverse events compared to 4.5 post procedure in-hospital days for the Zilver® PTX® group.

With regard to reducing hospital readmission rates, the applicant asserts that patients treated in the Eluvia™ group experienced reduced rates of hospital readmission following the index procedure compared to those in the Zilver® PTX® group. Hospital readmission rates at 12 months were 3.9% for the Eluvia™ group compared to 7.1% for the Zilver® PTX® group. Similar results were noted at 1 and 6 months; 1.0% vs 2.6% and 2.4% vs 3.8% respectively.

With regard to reducing the rate of device related complications, the applicant asserts that while the rates of adverse events were similar in total between treatment arms in the IMPERIAL study, there were measurable differences in device-related complications. Device-related adverse-events were reported in 8% of patients in the Eluvia™ group compared to 14% of patients in the Zilver® PTX® group.

Lastly, with regard to achieving similar functional outcomes and EQ–5D index values, while associated with half the rate of TLRs, the applicant asserts that narrowed or blocked arteries within the SFA can limit the supply of oxygen-rich blood throughout the lower extremities, causing pain or discomfort when walking. The applicant further asserts that performing physical activities is often challenging because of decreased blood supply to the legs, typically causing symptoms to become more challenging overtime unless treated. The applicant asserts that while functional outcomes appear similar between the Eluvia™ 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.[164] At 12 months, of the patients with complete Rutherford assessment data, 241 (86 percent) of 281 patients in the Eluvia™ group and 120 (85 percent) of 142 patients in the Zilver® PTX® group had symptoms reported as Rutherford Category 0 or 1 (none to mild claudication). The mean ankle-brachial index was 1·0 (SD 0·2) in both groups at 12 months (baseline mean ankle-brachial index 0·7 [SD 0·2] for Eluvia™ 0·8 [0·2] for Zilver® PTX®), with sustained hemodynamic improvement for approximately 80 percent of the patients in both groups. Walking function improved significantly from baseline to 12 months in both groups, as measured with the Walking Impairment Questionnaire and the 6-minute walk test. In both groups, the majority of patients had sustained improvement in the mobility dimension of the EQ–5D and roughly half had sustained improvement in the pain or discomfort dimension. No significant between-group differences were observed in the Walking Impairment Questionnaire, 6-minute walk test, or EQ–5D. Secondary endpoint results for the Eluvia™ stent and Zilver® PTX® stent groups are as follows:

- Hemodynamic improvement in walking—80.8 percent versus 78.7 percent;
- Walking impairment questionnaire scores (change from baseline)—40.8 (36.5) versus 35.8 (39.5);
- Distance (change from baseline)—33.2 (38.3) versus 29.5 (38.2);
- Speed (change from baseline)—18.3 (29.5) versus 18.1 (28.7);
- Stair climbing (change from baseline)—19.4 (36.7) versus 21.1 (34.6); and
- 6-Minute walk test distance (m) (change from baseline)—44.5 (119.5) versus 51.8 (130.5).

As summarized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42230), in our discussion of the comments

[163] Forrester JS, Fishbein M, Helfant R, Fagin J. 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.

[164] Gray WA, Keirse K, Soga Y, et al. A polymer-coated, paclitaxel-eluting stent (Eluvia) versus a polymer-free, paclitaxel-coated stent (Zilver PTX) for endovascular femoropopliteal intervention (IMPERIAL): A randomized, non-inferiority trial. Lancet 2018; published online Sept 22. *http://dx.doi.org/10.1016/S0140-6736(18)32262-1.*

received regarding substantial clinical improvement with respect to the new technology add-on payment application for Eluvia™ for FY 2020, we received a comment expressing safety concerns with paclitaxel-coated devices used to treat PAD. The commenter stated they were aware of an FDA alert concerning paclitaxel-coated devices. The commenter stated the applicant and other manufacturers of devices using paclitaxel should consider an alternative to paclitaxel.

We stated in response that we are aware of FDA's March 15, 2019 letter to healthcare providers regarding the ''Treatment of Peripheral Arterial Disease with Paclitaxel-Coated Balloons and Paclitaxel-Eluting Stents Potentially Associated with Increased Mortality.'' We noted that in March 2019, FDA conducted a preliminary analysis of long-term follow-up data (up to 5 years in some studies) of the pivotal premarket randomized trials for paclitaxel-coated products indicated for PAD. We stated that while the analyses are ongoing, according to FDA, the preliminary review of the data had identified a potentially concerning signal of increased long-term mortality in study subjects treated with paclitaxel-coated products compared to patients treated with uncoated devices.[165] Of the three trials with 5-year follow-up data, each showed higher mortality in subjects treated with paclitaxel-coated products than subjects treated with uncoated devices. In total, among the 975 subjects in these 3 trials, there was an approximately 50 percent increased risk of mortality in subjects treated with paclitaxel-coated devices versus those treated with control devices (20.1 percent versus 13.4 percent crude risk of death at 5 years).

We also noted that FDA stated that the data should be interpreted with caution for several reasons. First, there is large variability in the risk estimate of mortality due to the limited amount of long-term data. Second, the studies were not originally designed to be pooled, introducing greater uncertainty in the results. Third, the specific cause and mechanism of the increased mortality is unknown.

We further stated that based on the preliminary review of available data, FDA made the following recommendations regarding the use of paclitaxel-coated balloons and paclitaxel-eluting stents: That health care providers consider the following until further information is available; continue diligent monitoring of patients who have been treated with paclitaxel-coated balloons and paclitaxel-eluting stents; when making treatment recommendations and as part of the informed consent process, consider that there may be an increased rate of long-term mortality in patients treated with paclitaxel-coated balloons and paclitaxel-eluting stents; discuss the risks and benefits of all available PAD treatment options with your patients; for most patients, alternative treatment options to paclitaxel-coated balloons and paclitaxel-eluting stents should generally be used until additional analysis of the safety signal has been performed; for some individual patients at particularly high risk for restenosis, clinicians may determine that the benefits of using a paclitaxel-coated product may outweigh the risks; ensure patients receive optimal medical therapy for PAD and other cardiovascular risk factors as well as guidance on healthy lifestyles including weight control, smoking cessation, and exercise.

We also noted that FDA further stated that paclitaxel-coated balloons and stents are known to improve blood flow to the legs and decrease the likelihood of repeat procedures to reopen blocked blood vessels. However, because of this concerning safety signal, FDA stated that it believes alternative treatment options should generally be used for most patients while FDA continues to further evaluate the increased long-term mortality signal and its impact on the overall benefit-risk profile of these devices. FDA stated it intends to conduct additional analyses to determine whether the benefits continue to outweigh the risks for approved paclitaxel-coated balloons and paclitaxel-eluting stents when used in accordance with their indications for use. FDA stated it will also evaluate whether these analyses impact the safety of patients treated with these devices for other indications, such as treatment of arteriovenous access stenosis or critical limb ischemia.

Furthermore, we stated that because of concerns regarding this issue, FDA convened an Advisory Committee meeting of the Circulatory System Devices Panel on June 19 and 20, 2019 to: Facilitate a public, transparent, and unbiased discussion on the presence and magnitude of a long-term mortality signal; discuss plausible reasons, including any potential biological mechanisms, for a long-term mortality signal; re-examine the benefit-risk profile of this group of devices; consider modifications to ongoing and future US clinical trials evaluating devices containing paclitaxel, including added surveillance, updated informed consent, and enhanced adjudication for drug-related adverse events and deaths; and guide other regulatory actions, as needed. The June 19 and 20, 2019 Advisory Committee meeting of the Circulatory System Devices Panel concluded that analyses of available data from FDA-approved devices show an increase in late mortality (between 2 and 5 years) associated with paclitaxel-coated devices intended to treat femoropopliteal disease.[166] However, causality for the late mortality rate increase could not be determined. Additional data may be needed to further assess the magnitude of the late mortality signal, determine any potential causes, identify patient subgroups that may be at greater risk, and to update benefit-risk considerations of this device class.[167]

We stated that FDA continues to recommend that health care providers report any adverse events or suspected adverse events experienced with the use of paclitaxel-coated balloons and paclitaxel-eluting stents. FDA stated that it will keep the public informed as any new information or recommendations become available.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42231), after consideration of the public comments we received and the latest available information from the FDA advisory panel, we noted the FDA panel's preliminary review of the data had identified a potentially concerning signal of increased long-term mortality in study subjects treated with paclitaxel-coated products compared to patients treated with uncoated devices. We stated that additionally, since FDA has stated that it believes alternative treatment options should generally be used for most patients while it continues to further evaluate the increased long-term mortality signal and its impact on the overall benefit-risk profile of these devices, we remained concerned that we did not have enough information to determine that the Eluvia™ device represents a substantial clinical improvement over existing technologies. Therefore, we stated that we were not approving the Eluvia™ device for FY 2020 new technology add-on payments. We also stated that we would monitor any new information or

[165] *https://www.fda.gov/medical-devices/letters-health-care-providers/update-treatment-peripheral-arterial-disease-paclitaxel-coated-balloons-and-paclitaxel-eluting.*

[166] *https://www.fda.gov/advisory-committees/advisory-committee-calendar/june-19-20-2019-circulatory-system-devices-panel-medical-devices-advisory-committee-meeting#event-materials.*

[167] *https://www.fda.gov/advisory-committees/advisory-committee-calendar/june-19-20-2019-circulatory-system-devices-panel-medical-devices-advisory-committee-meeting#event-materials.*

recommendations as they become available.

Since the FY 2020 IPPS/LTCH PPS final rule, the FDA issued an August 7, 2019 update: ''Treatment of Peripheral Arterial Disease with Paclitaxel-Coated Balloons and Paclitaxel-Eluting Stents Potentially Associated with Increased Mortality.'' [168] In its update, the FDA included recommendations to healthcare providers for assessing and treating patients with PAD using paclitaxel-coated devices. Based on the FDA's review of available data and the Advisory Panel conclusions, the FDA recommends that healthcare providers consider the following:

- Continue diligent monitoring of patients who have been treated with paclitaxel-coated balloons and paclitaxel-eluting stents.
- When making treatment recommendations, and as part of the informed consent process, consider that there may be an increased rate of long-term mortality in patients treated with paclitaxel-coated balloons and paclitaxel-eluting stents.
- Discuss the risks and benefits of all available PAD treatment options with your patients. For many patients, alternative treatment options to paclitaxel-coated balloons and paclitaxel-eluting stents provide a more favorable benefit-risk profile based on currently available information.
- 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.
- In discussing treatment options, physicians should explore their patients' expectations, concerns and treatment preferences.
- Ensure patients receive optimal medical therapy for PAD and other cardiovascular risk factors as well as guidance on healthy lifestyles including weight control, smoking cessation, and exercise.
- Report any adverse events or suspected adverse events experienced with the use of paclitaxel-coated balloons and paclitaxel-eluting stents.

In addition, the August 7, 2019 update noted the following. Based on the conclusions of its analysis and recommendations of the advisory panel, FDA stated that it is taking additional steps to address this signal, including working with manufacturers on updates to device labeling and clinical trial informed consent documents to incorporate information about the late mortality signal. FDA also stated that it is continuing to actively work with the manufacturers and investigators on additional clinical evidence development for assessment of the long-term safety of paclitaxel-coated devices. FDA noted that paclitaxel-coated balloons and stents improve blood flow to the legs and decrease the likelihood of repeat procedures to reopen blocked blood vessels compared to uncoated devices. The update stated that the panel 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).

The applicant stated in its FY 2021 application that while CMS denied the application for new technology add-on payments for Eluvia™ for FY 2020 because of its concerns about paclitaxel, the available evidence and policymaking from the FDA would suggest that this device is safe, effective and a substantial clinical improvement. To address the substantial clinical improvement concerns stated in the FY 2020 final rule, the applicant stated that Eluvia™ is not associated with increased all-cause mortality and that two-year all-cause mortality data are consistent with FDA-published rates for uncoated angioplasty devices. The applicant further asserted that most recent publications on peripheral paclitaxel-coated devices do not replicate the strong mortality signal identified in the meta-analysis. The applicant stated that it submitted information on Eluvia™ to the FDA for the June 19–20 Circulatory System Devices Panel of the Medical Devices Advisory Committee meeting. The applicant further asserted that the FDA continues to find that paclitaxel devices are effective, specifically that ''Paclitaxel-coated balloons and stents improve blood flow to the legs and decrease the likelihood of repeat procedures to reopen blocked blood vessels compared to uncoated devices.'' [169] The applicant stated that the FDA, following months of investigation, multiple letters to health care providers and an advisory panel meeting, has not changed the marketed status of peripheral paclitaxel devices. Therefore, the applicant respectfully requested that CMS consider that Eluvia™ satisfies the substantial clinical improvement criterion in light of this information. The applicant referred to the FDA's meta-analysis of long-term follow-up data from the pivotal premarket randomized trials for paclitaxel-coated devices used to treat PAD. The FDA's meta-analysis of these trials [170] identified a late mortality signal in study subjects treated with paclitaxel-coated devices compared to patients treated with uncoated devices. Specifically, in three randomized trials which enrolled a total of 1090 patients, the crude mortality rate at 5 years was 19.8% (range 15.9%–23.4%) in patients treated with paclitaxel-coated devices compared to 12.7% (range 11.2%–14.0%) in subjects treated with uncoated devices. The relative risk for increased mortality at 5 years was 1.57 (95% confidence interval 1.16—2.13), which corresponds to a 57% relative increase in mortality in patients treated with paclitaxel-coated devices.

In its application for FY 2021, the applicant stated that they respectfully disagree with CMS's conclusion that Eluvia™ did not satisfy the substantial clinical improvement criterion as the IMPERIAL randomized controlled trial demonstrates superiority over the closest comparative device. In its application for FY 2021, in response to these concerns related to peripheral paclitaxel devices, the applicant referred to the updated bulletin FDA issued in August 2019 to provide the latest information on its analysis of long-term follow-up data from premarket trials and to provide summary information from its June 2019 advisory panel meeting. Specifically, the applicant noted that FDA stated that paclitaxel-coated balloons and stents improve blood flow to the legs and decrease the likelihood of repeat procedures to reopen blocked blood vessels compared to uncoated devices. The June 2019 advisory panel 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).

The applicant also noted that it has worked closely with FDA to address questions about the late mortality signal associated with some peripheral paclitaxel-coated devices, as identified in the meta-analysis. The applicant

[168] *https://www.fda.gov/medical-devices/letters-health-care-providers/august-7-2019-update-treatment-peripheral-arterial-disease-paclitaxel-coated-balloons-and-paclitaxel.*

[169] FDA Letter to Health Care Providers, August 7, 2019. Last accessed at *https://www.fda.gov/medical-devices/letters-health-care-providers/august-7-2019-update-treatment-peripheral-arterial-disease-paclitaxel-coated-balloons-and-paclitaxel* on September 10, 2019.

[170] *https://www.fda.gov/medical-devices/letters-health-care-providers/update-treatment-peripheral-arterial-disease-paclitaxel-coated-balloons-and-paclitaxel-eluting.*

noted that Eluvia™ was not included in the meta-analysis.

Additionally, the applicant stated that it has demonstrated (a) the absence of a mortality signal with Eluvia™ and (b) the absence of a mortality signal with sustained-release drug eluting paclitaxel stent technology in the large long-term data for the TAXUS coronary stent.[171]

With regard to the absence of a mortality signal with Eluvia™, the applicant further stated that Eluvia™ is not associated with increased all-cause mortality. The applicant explained that Eluvia™ shows no mortality signal at 2 years in over 300 patients. Additionally, the applicant noted that its parent company Boston Scientific has extensive experience with sustained-release paclitaxel-eluting stent technology and noted that TAXUS has over 10 years of clinical data, with long-term mortality in clinical trials following approximately 2,800 patients, without an observed mortality signal.

As it relates to Eluvia™, the applicant stated that findings of the FDA analysis should be interpreted with caution for several reasons. First, Eluvia™ was not included in the FDA meta-analysis. Second, the applicant stated the analysis failed to find any plausible mechanism that could explain the observed mortality signal. Third, the applicant asserted that the analysis contained structural flaws that may have contributed to its findings, including small sample size, presence of ascertainment bias and lack of patient level data.

The applicant added that additional analyses have been conducted since the publication of the meta-analysis. In a Medicare claims analysis of over 150,000 patients who underwent femoropopliteal artery revascularization, the applicant noted that no mortality signal was seen in the group treated with paclitaxel-coated devices.[172] According to the applicant, this finding was echoed by other studies.

Finally, the applicant stated that it believes the FDA recognized the value of allowing physicians to treat their PAD patients with paclitaxel devices in its letter published on August 7, 2019, acknowledging the signal in the meta-analysis and recognizing the benefits that paclitaxel devices offer for these patients.

In summary, the applicant stated that Eluvia™ should be approved for new technology add-on payments based on the following:

- Updated August 2019 FDA letter to providers issued after the FY 2020 IPPS/LTCH PPS final rule, maintaining peripheral paclitaxel devices on the market;
- Multiple recently published studies [173] [174] demonstrating the absence of increased mortality associated with peripheral paclitaxel devices;
- An analysis of over 150,000 Medicare beneficiaries, designed with FDA input, demonstrating no difference in mortality between patients treated with peripheral paclitaxel devices compared to those treated without paclitaxel devices;
- Confounding factors in the 2018 JAHA Katsanos et al. meta-analysis (meta-analysis) [175] and ascertainment bias, as highlighted at the 2019 Vascular Leaders Forum,[176] and no plausible mechanism has been identified for increased mortality;
- The rate of mortality for patients treated with Eluvia™ at 2 years is consistent with the rate of non-paclitaxel-based peripheral devices.[177]

Although the Eluvia™ system was not included in the meta-analysis, we remain concerned with the conclusion of the meta-analysis results. Specifically, we are concerned with the conclusion that there is an increased risk of death following application of paclitaxel-coated balloons and stents in the femoropopliteal artery of the lower limb and how it impacts substantial clinical improvement for the Eluvia™ system.

We also note the FDA's statement in the August 2019 letter that because of the demonstrated short-term benefits of the devices, the limitations of the available data, and uncertainty regarding the long-term benefit-risk profile of paclitaxel-coated devices, the FDA believes clinical studies of these devices may continue and should collect long-term safety (including mortality) and effectiveness data. Per the FDA, these studies require appropriate informed consent and close safety monitoring to protect enrolled patients.

Below, we summarize and respond to a written public comment we received during the open comment period regarding whether Eluvia™ meets the substantial clinical improvement criterion in response to the New Technology Town Hall meeting.

Comment: With regard to the applicant's claim that the Eluvia™ stent achieves statistically superior primary patency over Zilver® PTX®, the applicant provided the two-year results from the IMPERIAL global randomized controlled clinical trial, comparing Eluvia™ to Zilver® PTX®. The applicant asserts that Eluvia™ maintains higher primary patency than Zilver® PTX® at 2 years, 83.0% compared to 77.1%. The applicant contends that guidelines recognize the importance of primary patency in assessing the efficacy of peripheral endovascular therapies.[178] The applicant further asserts that Eluvia's™ two-year primary patency is the highest reported in a superficial femoral artery U.S. pivotal trial for a drug-eluting stent or drug-coated balloon.[179] The applicant stated that 2-year primary patency results are consistent with the 2-year target lesion revascularization (TLR) results released earlier in 2019.[180] According to the applicant, Eluvia™ sustained a statistically significant reduction in TLR at 2 years compared to

[171] Stone GW, Ellis SG, Colombo A, et al. Long-term safety and efficacy of paclitaxel-eluting stents final 5-year analysis from the TAXUS Clinical Trial Program. JACC Cardiovasc Interv. 2011;4(5):530–542.

[172] Secemsky EA at al. Drug-Eluting Stent Implantation and Long-Term Survival Following Peripheral Artery Revascularization. J Am Coll Cardiol. 2019 May 28;73(20):2636–2638.

[173] 18Spreen MI, Martens JM, Knippenberg B, et al. Long-Term Follow-up of the PADI Trial: Percutaneous Transluminal Angioplasty Versus Drug-Eluting Stents for Infrapopliteal Lesions in Critical Limb Ischemia. *J Am Heart Assoc.* 2017;6(4).

[174] UPDATE: Treatment of Peripheral Arterial Disease with Paclitaxel-Coated Balloons and Paclitaxel-Eluting Stents Potentially Associated with Increased Mortality—Letter to Health Care Providers. 2019; Last accessed at *https://www.fda.gov/MedicalDevices/Safety/LettertoHealthCareProviders/ucm633614.htm* on October 9, 2019.

[175] *https://www.ahajournals.org/doi/full/10.1161/JAHA.118.011245.*

[176] Varcoe R. Unintended Consequences of Various trial Designs, Potential Effect on Mortality and Other Outcomes. Vascular Leaders Forum, March 2019.

[177] Pooled all-cause mortality rate includes IMPERIAL and MAJESTIC Trials. 2-year all-cause mortality rate for IMPERIAL (includes IMPERIAL RCT, Long Lesion, and PK sub-studies) is 7.0%. MAJESTIC follow-up is final at 3 years. IMPERIAL follow-up is complete through 2 years and ongoing through 5 years. As-treated ELUVIA patients. FDA PTA reference based on FDA Executive Summary. Two-year mortality rate within the PTA arm of ILLUMENATE was 7.4% and within the PTA arm of IN.PACT SFA was 1.0%.

[178] Writing Committee Members, Gerhard-Herman MD, Gornik HL et al. 2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Artery Disease: Executive Summary. Vasc Med. 2017 Jun;22(3):NP1–NP43.

[179] Highest two-year primary patency based on 24-month Kaplan-Meier estimates reported for IMPERIAL, IN.PACT SFA, ILLUMENATE, LEVANT II and Primary Randomization for Zilver PTX RCT.

[180] BSC Data on File. As-treated ELUVIA and PTxControl data from IMPERIAL RCT.FDA PTA reference based on FDA Executive Summary (median of PTA arms). Abbreviations: DES, drug-eluting stent; TLR, target lesion revascularization; PTx, paclitaxel.

Zilver PTX, 12.9% vs. 20.5% (p=0.0472).[181]

Response: We appreciate the applicant's input. We will take these comments into consideration when deciding whether to approve new technology add-on payments for Eluvia™ for FY 2021.

f. GammaTile

GT Medical Technologies, Inc. submitted an application for new technology add-on payments for FY 2021 for the GammaTile™. We note that Isoray Medical, Inc. and GammaTile, LLC previously submitted an application for new technology add-on payments for GammaTile™ for FY 2018, which was withdrawn, and also for FY 2019, however the technology did not receive FDA approval or clearance by July 1, 2018 and, therefore, was not eligible for consideration for new technology add-on payments for FY 2019. GT Medical Technologies, Inc. submitted an application for FY 2020, which was not approved as CMS was unable to make a determination that GammaTile™ technology represents a substantial clinical improvement over existing therapies.

The GammaTile™ is a brachytherapy device for use in the treatment of patients who have been diagnosed with recurrent intracranial neoplasms, which uses cesium-131 radioactive sources embedded in a collagen matrix. GammaTile™ is designed to provide adjuvant radiation therapy to eliminate remaining tumor cells in patients who required surgical resection of recurrent brain tumors. According to the applicant, the GammaTile™ constitutes a new form of internal radiation, with collagen tile structural offsets acting as an internal compensator for the delivery of cesium-131 brachytherapy sources embedded within the product. The applicant stated that the technology has been manufactured for use in the setting of a craniotomy resection site where there is a high chance of local recurrence of a Central Nervous System (CNS) or dual-based tumor. The applicant asserted that the use of the GammaTile™ technology provides a new, unique modality for treating patients who require radiation therapy to augment surgical resection of malignancies of the brain. By offsetting the radiation sources with a 3 mm gap of a collagen matrix, the applicant asserted that the use of the GammaTile™ technology resolves issues with ''hot'' and ''cold'' spots associated with brachytherapy, improves safety, and potentially offers a treatment option for patients with limited or no other available options. The GammaTile™ is biocompatible and bioabsorbable, and is left in the body permanently without need for future surgical removal. The applicant asserted that the commercial manufacturing of the product will significantly improve on the process of constructing customized implants with greater speed, efficiency, and accuracy than is currently available, and requires less surgical expertise in placement of the radioactive sources, allowing a greater number of surgeons to utilize brachytherapy techniques in a wider variety of hospital settings.

The GammaTile™ technology received FDA Section 510(k) clearance as a medical device on July 6, 2018. According to the applicant, due to finalization of design and manufacturing activities, the technology was not commercially available until January of 2019. Subsequently, the FDA cleared GammaTile™ as a Class II medical device under the corporate name of GT Medical Technologies, Inc. on March 13, 2019. The cleared indications for use state that GammaTile™ is intended to deliver radiation therapy (brachytherapy) in patients who have been diagnosed with recurrent intercranial neoplasms. The applicant submitted a request for approval for a unique ICD–10–PCS code for the use of the GammaTile™ technology, which was approved effective October 1, 2017 (FY 2018). The ICD–10–PCS procedure code used to identify procedures involving the use of the GammaTile™ technology is 00H004Z (Insertion of radioactive element, cesium-131 collagen implant into brain, open approach).

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would therefore not be considered ''new'' for purposes of new technology add-on payments. We note that in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42261), we stated that after consideration of comments, we believe that the GammaTile™ mechanism of action is different from current forms of radiation therapy and brachytherapy as it is the first FDA cleared device to use a manufactured collagen matrix which offsets radiation sources for use for the treatment of recurrent intracranial neoplasms. Therefore, we stated that the GammaTile™ is not substantially similar to existing brachytherapy technology and meets the newness criterion. We refer the reader to the FY 2020 final rule for the complete discussion of how the GammaTile™ meets the newness criterion. We welcome any additional information or comments in response to this proposed rule regarding whether the GammaTile™ is substantially similar to an existing technology and whether it meets the newness criterion for purposes of its application for new technology add-on payments for FY 2021.

With regard to the cost criterion, the applicant conducted the following analysis. The applicant worked with the Barrow Neurological Institute at St. Joseph's Hospital and Medical Center (St. Joseph's) to obtain actual claims from mid-2015 through mid-2016 for craniotomies that did not involve placement of the GammaTile™ technology. The cases were assigned to MS–DRGs 025, 026, and 027 (Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively). For the 460 claims, the average case-weighted unstandardized charge per case was $143,831. The applicant standardized the charges for each case and inflated each case's charges by applying the outlier charge inflation factor of 1.054 included in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42629) by the age of each case (that is, the factor was applied to 2015 claims 4 times and 2016 claims 3 times). The applicant then calculated an estimate for ancillary charges associated with placement of the GammaTile™ device, as well as standardized charges for the GammaTile™ device itself. The applicant determined it meets the cost criterion because the final inflated average case-weighted standardized charge per case (including the charges associated with the GammaTile™ device) of $270,445 exceeds the average case-weighted threshold amount of $151,193 for MS–DRG 023 (Craniotomy with Major Device Implant or Acute Complex CNS PDX with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator), the MS–DRG that would be assigned for cases involving the GammaTile™ device.

The applicant stated that its analysis does not include a reduction in costs due to reduced operating room times. According to the applicant, the cost analysis reflects the time associated with a craniotomy and device placement. The applicant does not anticipate any reduction in operating room time relative to prior operative methods. We invite public comments on

[181] Boston Scientific Presentation to the Circulatory System Devices Panel of the Medical Devices Advisory Committee Meeting, June 19, 2019.

whether the GammaTile™ technology meets the cost criterion.

With regard to substantial clinical improvement, the applicant stated that the GammaTile™ technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments for recurrent CNS malignancies and significantly improves clinical outcomes when compared to currently available treatment options. The applicant explained that therapeutic options for patients who have been diagnosed with large or recurrent brain metastases are limited (for example, stereotactic radiotherapy, additional EBRT, or systemic immunochemotherapy). However, according to the applicant, the GammaTile™ technology provides a treatment option for patients who have been diagnosed with radiosensitive recurrent brain tumors that are not eligible for treatment with any other currently available treatment options. Specifically, the applicant stated that the GammaTile™ device may provide the only radiation treatment option for patients who have been diagnosed with tumors located close to sensitive vital brain sites (for example, brain stem) and patients who have been diagnosed with recurrent brain tumors who may not be eligible for additional treatment involving the use of external beam radiation therapy. There is a lifetime limit for the amount of radiation therapy a specific area of the body can receive. Patients whose previous treatment includes external beam radiation therapy may be precluded from receiving high doses of radiation associated with subsequent external beam radiation therapy, and the GammaTile™ technology can also be used to treat tumors that are too large for treatment with external beam radiation therapy. According to the applicant, patients who have been diagnosed with these large tumors are not eligible for treatment with external beam radiation therapy because the radiation dose to healthy brain tissue would be too high.

The applicant summarized how the GammaTile™ technology improves clinical outcomes compared to existing treatment options, including external beam radiation therapy and other forms of brain brachytherapy as: (1) Providing a treatment option for patients with no other available treatment options; (2) reducing the rate of mortality compared to alternative treatment options; (3) reducing the rate of radiation necrosis; (4) reducing the need for re-operation; (5) reducing the need for additional hospital visits and procedures; and (6) providing more rapid beneficial resolution of the disease process treatment.

The applicant cited several sources of data to support these assertions. The applicant referenced a paper by Brachman, Dardis et al., which was published in the *Journal of Neurosurgery* on December 21, 2018.[182] This study, a follow-up on the progress of 20 patients with recurrent previously irradiated meningiomasis, is a feasibility or superior progression-free survival study comparing the patient's own historical control rate against subsequent treatment with GammaTile™.

An additional source of clinical data is from Gamma Tech's internal review of data from two centers treating brain tumors with GammaTile™; The two centers are the Barrow Neurological Institute (BNI) at St. Joseph's Hospital and St. Joseph's Medical Center, Phoenix, AZ, and this internal review is referred to here as the ''BNI'' study.[183] The BNI study summarized Gamma Tech's experience with the GammaTile™ technology. The applicant also included a reference to its updated study, described on *ClinicalTrials.gov* under NCT03088579, which includes 79 recurrent, previously irradiated intracranial neoplasms.

Another source of data that the applicant cited to support its assertions regarding substantial clinical improvement is an abstract by Pinnaduwage, D., et al. Also submitted in the application were abstracts from 2014 through 2018 in which updates from the progression-free survival study and the BNI study were presented at specialty society clinical conferences. The following summarizes the findings cited by the applicant to support its assertions regarding substantial clinical improvement.

Regarding the assertion of local control, the 2018 article which was published in the *Journal of Neurosurgery* found that, with a median follow-up of 15.4 months (range 0.03–47.5 months), there were 2 reported cases of recurrence out of 20 meningiomas, with median treatment site progression time after surgery and brachytherapy with the GammaTile™ precursor and prototype devices not yet being reached, compared to 18.3 months in prior instances. Median overall survival after resection and brachytherapy was 26 months, with 9 patient deaths. In a presentation at the Society for Neuro-Oncology in November 2014,[184] the outcomes of 20 patients who were diagnosed with 27 tumors covering a variety of histological types treated with the GammaTile™ prototype were presented. The applicant noted the following with regard to the patients: (1) All tumors were intracranial, supratentorial masses and included low- and high-grade meningiomas, metastases from various primary cancers, high-grade gliomas, and others; (2) all treated masses were recurrent following treatment with surgery and/or radiation and the group averaged two prior craniotomies and two prior courses of external beam radiation treatment; and (3) following surgical excision, the prototype GammaTile™ were placed in the resection cavity to deliver a dose of 60 Gray to a depth of 5 mm of tissue; and (4) all patients had previously experienced regrowth of their tumors at the site of treatment and the local control rate of patients entering the study was 0 percent.

With regard to outcomes, the applicant stated that, after their initial treatment, patients had a median progression-free survival time of 5.8 months; post treatment with the prototype GammaTile™, at the time of this analysis, only 1 patient had progressed at the treatment site, for a local control rate of 96 percent; and median progression-free survival time, a measure of how long a patient lives without recurrence of the treated tumor, had not been reached (as this value can only be calculated when more than 50 percent of treated patients have failed the prescribed treatment).

The applicant stated that it received two peer-reviewed awards for comprehensive clinical trial reporting on the treatment of 79 recurrent brain tumors treated with GammaTile. The applicant provided a recent summary presentation titled: ''Surgically Targeted Radiation Therapy: A Prospective Trial in 79 Recurrent, Previously Irradiated Intracranial Neoplasms.'' at *The American Brachytherapy Society*.[185] The clinical endpoints included time to

[182] Brachman, D., et al., ''Resection and permanent intracranial brachytherpay using modular, biocompatible cesium-131 implants: Results in 20 recurrent previously irradiated meningiomas,'' *J Neurosurgery,* December 21, 2018.

[183] Brachman, D., et al., ''Surgery and Permanent Intraoperative Brachytherapy Improves Time to Progress of Recurrent Intracranial Neoplasms,'' Society for Neuro-Oncology Conference on Meningioma, June 2016.

[184] Dardis, C., ''Surgery and Permanent Intraoperative Brachytherapy Improves Times to Progression of Recurrent Intracranial Neoplasms,'' Society for Neuro-Oncology, November 2014.

[185] Brachman D, Youssef E, Dardis C, et al.: Surgically Targeted Radiation Therapy: Safety Profile of Collagen Tile Brachytherapy in 79 Recurrent, Previously Irradiated Intracranial Neoplasms on a Prospective Clinical Trial. Brachytherapy 18 (2019) S35–36.

tumor progression and survival, which the applicant stated provided objective, clinically important measures. The median local control after GammaTile therapy versus prior treatment was 12.0 versus 9.5 months for high-grade glioma patients (p=0.13) and 48.8 months versus 23.3 months for menigioma patients (p=0.01). For the metastasis patients, the median local control had not been reached versus 5.1 months with prior treatment (p=0.02). The median overall survival was 12.0 months for high grade glioma patients, 12.0 months for brain metastasis patients, and 49.2 months for the meningioma patients. According to the applicant, these data demonstrate dramatic, clinically meaningful difference in Kaplan-Meier curves comparing time to local recurrence at same site in the same patients. The applicant stated that GammaTile™ is significantly outperforming the initial therapies attempted in this patient population.

The applicant also cited the findings from Brachman, et al. to support local control of recurrent brain tumors. At the Society for Neuro-Oncology Conference on Meningioma in June 2016,[186] a second set of outcomes on the prototype GammaTile™ was presented. This study enrolled 16 patients with 20 recurrent Grade II or III meningiomas, who had undergone prior surgical excision external beam radiation therapy. These patients underwent surgical excision of the tumor, followed by adjuvant radiation therapy with the prototype GammaTile™. The applicant noted the following outcomes (1) of the 20 treated tumors, 19 showed no evidence of radiographic progression at last follow-up, yielding a local control rate of 95 percent; 2 of the 20 patients exhibited radiation necrosis (1 symptomatic, 1 asymptomatic); and (2) the median time to failure from the prior treatment with external beam radiation therapy was 10.3 months and after treatment with the prototype GammaTile™ only 1 patient failed at 18.2 months. Therefore, according to the applicant, the median treatment site progression-free survival time after the prototype GammaTile™ treatment had not yet been reached (average follow-up of 16.7 months, range 1 to 37 months).

A third prospective study was accepted for presentation at the November 2016 Society for Neuro-Oncology annual meeting.[187] In this study, 13 patients who were diagnosed with recurrent high-grade gliomas (9 with glioblastoma and 4 with Grade III astrocytoma) were treated in an identical manner to the cases previously described. Previously, all patients had failed the international standard treatment for high-grade glioma, a combination of surgery, radiation therapy, and chemotherapy referred to as the ''Stupp regimen.'' For the prior therapy, the median time to failure was 9.2 months (range 1 to 40 months). After therapy with a prototype GammaTile™, the applicant noted the following: (1) The median time to same site local failure had not been reached and 1 failure was seen at 18 months (local control 92 percent); and (2) with a median follow-up time of 8.1 months (range 1 to 23 months) 1 symptomatic patient (8 percent) and 2 asymptomatic patients (15 percent) had radiation-related MRI changes. However, no patients required re-operation for radiation necrosis or wound breakdown. Dr. Youssef was accepted to present at the 2017 Society for Neuro-Oncology annual meeting, where he provided an update of 58 tumors treated with the GammaTile™ technology. At a median whole group follow-up of 10.8 months, 12 patients (20 percent) had a local recurrence at an average of 11.33 months after implant. Six- and 18-month recurrence-free survival was 90 percent and 65 percent, respectively. Five patients had complications, at a rate that was equal to or lower than rates previously published for patients without access to the GammaTile™ technology.

In support of its assertion of a reduction in radiation necrosis, the applicant also included discussion of a presentation by D.S. Pinnaduwage, Ph.D., at the August 2017 annual meeting of the American Association of Physicists in Medicine. Dr. Pinnaduwage compared the brain radiation dose of the GammaTile™ technology with other radioactive seed sources. Iodine-125 and palladium-103 were substituted in place of the cesium-131 seeds. The study reported findings that other radioactive sources reported higher rates of radiation necrosis and that ''hot spots'' increased with larger tumor size, further limiting the use of these isotopes. The study concluded that the larger high-dose volume with palladium-103 and iodine-125 potentially increases the risk for radiation necrosis, and the inhomogeneity becomes more pronounced with increasing target volume. The applicant also cited a presentation by Dr. Pinnaduwage at the August 2018 annual meeting of the American Association of Physicists in Medicine, in which research findings demonstrated that seed migration in collagen tile implantations was relatively small for all tested isotopes, with Cesium-13 showing the least amount of seed migration.

The applicant asserted that, when considered in total, the data reported in these presentations and studies and the intermittent data presented in their abstracts support the conclusion that a significant therapeutic effect results from the addition of GammaTile™ radiation therapy to the site of surgical removal. According to the applicant, the fact that these patients had failed prior best available treatments (aggressive surgical and adjuvant radiation management) presents the unusual scenario of a salvage therapy outperforming the current standard of care. The applicant noted that follow-up data continues to accrue on these patients.

Regarding the assertion that GammaTile™ reduces mortality, the applicant stated that the use of the GammaTile™ technology reduces rates of mortality compared to alternative treatment options. The applicant explained that studies on the GammaTile™ technology have shown improved local control of tumor recurrence. According to the applicant, the results of these studies showed local control rates of 92 percent to 96 percent for tumor sites that had local control rates of 0 percent from previous treatment. The applicant noted that these studies also have not reached median progression-free survival time with follow-up times ranging from 1 to 37 months. Previous treatment at these same sites resulted in median progression-free survival times of 5.8 to 10.3 months.

The applicant further stated that the use of the GammaTile™ technology reduces rates of radiation necrosis compared to alternative treatment options. The applicant explained that the rate of symptomatic radiation necrosis in the GammaTile™ clinical studies of 5 to 8 percent is substantially lower than the 26 percent to 57 percent rate of symptomatic radiation necrosis requiring re-operation historically associated with brain brachytherapy, and lower than the rates reported for initial treatment of similar tumors with modern external beam and stereotactic radiation techniques. The applicant

[186] Brachman, D., et al., ''Surgery and Permanent Intraoperative Brachytherapy Improves Time to Progress of Recurrent Intracranial Neoplasms,'' Society for Neuro-Oncology Conference on Meningioma, June 2016.

[187] Youssef, E., ''C–131 Implants for Salvage Therapy of Recurrent High Grade Gliomas,'' Society for Neuro-Oncology Annual Meeting, November 2016.

indicated that this is consistent with the customized and ideal distribution of radiation therapy provided by the GammaTile™ technology.

The applicant also asserted that the use of the GammaTile™ technology reduces the need for re-operation compared to alternative treatment options. The applicant explained that patients receiving a craniotomy, followed by external beam radiation therapy or brachytherapy, could require re-operation in the following three scenarios:

- Tumor recurrence at the excision site could require additional surgical removal;
- Symptomatic radiation necrosis could require excision of the affected tissue; and
- Certain forms of brain brachytherapy require the removal of brachytherapy sources after a given period of time.

However, according to the applicant, because of the high local control rates, low rates of symptomatic radiation necrosis, and short half-life of cesium-131, the GammaTile™ technology will reduce the need for re-operation compared to external beam radiation therapy and other forms of brain brachytherapy.

Additionally, the applicant stated that the use of the GammaTile™ technology reduces the need for additional hospital visits and procedures compared to alternative treatment options. The applicant noted that the GammaTile™ technology is placed during surgery, and does not require any additional visits or procedures. The applicant contrasted this improvement with external beam radiation therapy, which is often delivered in multiple fractions that must be administered over multiple days. The applicant provided an example where whole brain radiotherapy (WBRT) is delivered over 2 to 3 weeks, while the placement of the GammaTile™ technology occurs during the craniotomy and does not add any time to a patient's recovery.

Based on consideration of all of the previously presented data, the applicant believed that the use of the GammaTile™ technology represents a substantial clinical improvement over existing technologies. We note that the clinical data submitted to date in connection with its application for new technology add-on payments for FY 2021 is essentially identical to what was submitted in connection with its application for new technology add-on payments for FY 2020. As we indicated in previous rulemaking (84 FR 42260 through 42265), the findings presented appear to be derived from relatively small case-studies and not data from clinical trials conducted under an FDA-approved investigational device exemption application. We note that the study performed on 74 patients with 79 tumors was a single-arm and single-institution study, where each patient functioned as their own control and the study goal was to compare the time to local recurrence after GammaTile™ treatment to the time of local recurrence after initial treatment of intracranial tumors. That is, the control arm were patients treated for initial intracranial brain tumors, and the treatment arm or the GammaTile™ treatment arm were the same control patients now experiencing local recurrent intracranial brain tumors in the same site with the same brain tumor type. In this clinical trial, the applicant compared the time from initial treatment to first local recurrence (control arm) vs. time from GammaTile™ treatment of first local recurrence to second local recurrence of the same brain tumor site and tumor type. There was a statistically significant difference between the control arm treatment and GammaTile™ treatment for patients with recurrent meningioma and brain metastases and no statistically significant difference between the control arm treatment and GammaTile™ treatment for patients with recurrent high-grade glioma.

We continue to have concerns that, while the applicant described increases in median time to disease recurrence for certain intra-cranial tumors (in a small number of patients with different histologies) in support of clinical improvement, the lack of analysis, meta-analysis, or statistical tests indicates that the clinical efficacy and safety data for seeded brachytherapy is limited. While we acknowledge the difficulty in establishing randomized control groups in studies involving recurrent brain tumors, we are concerned that GammaTile™ technology does not represent a substantial clinical improvement over existing therapies and requires additional clinical data to demonstrate substantial clinical improvement. We note that the applicant has stated its intention to provide additional clinical data and information in connection with its application for new technology add-on payments for FY 2021, potentially including an update on patient outcomes from the completed clinical trial (ClinicalTrials.gov, NCT03088579), additional clinical data from early adopting locations, and additional meta-analysis to address the concerns previously raised by CMS.

We invite public comments on whether the GammaTile™ technology meets the substantial clinical improvement criterion. We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for GammaTile™ or at the New Technology Town Hall meeting.

g. Hemospray® Endoscopic Hemostat

Cook Medical submitted an application for new technology add-on payments for the Hemospray® Endoscopic Hemostat (Hemospray) for FY 2021. According to the applicant, Hemospray is indicated by the FDA for hemostasis of nonvariceal gastrointestinal bleeding. Using an endoscope to access the gastrointestinal tract, the Hemospray delivery system is passed through the accessory channel of the endoscope and positioned just above the bleeding site without making contact with the GI tract wall. The Hemospray powder, Bentonite, is propelled through the application catheter, either a 7 or 10 French polyethylene catheter, by release of CO_2 from the cartridge located in the device handle and sprayed onto the bleeding site. Bentonite can absorb 5 to 10 times its weight in water and swell up to 15 times its dry volume. Bentonite rapidly absorbs water and becomes cohesive to itself and adhesive to tissue forming a physical barrier to aqueous fluid (for example, blood). Hemospray is not absorbed by the body and does not require removal as it passes through the GI tract within 72 hours. Hemospray is single use and disposable.

According to the applicant, current standard of care hemostatic modalities used for the management of nonvariceal gastrointestinal bleeding have a failure rate of 8 to 15 percent and a rebleeding rate of 10 to 25 percent, or worse, depending on patient etiology and morbidity.[188] The applicant asserted that the risk of morbidity, mortality, and rebleeding can be predicted using validated scoring methods such as the Rockall Score (RS).[189] Cancerous lesions, which are more frequently identified as a result of advances in locating and determining the cause of

[188] Lau J, Barkun A, Fan D, Kuipers E, Yang Y, Chan F. Challenges in the management of acute peptic ulcer bleeding. Lancet 2013; 381: 2033–43.

[189] Mokhtare M, Bozorgi V, Agah S et al. Comparison of Glasgow-Blatchford score and full Rockall score systems to predict clinical outcomes in patients with upper gastrointestinal bleeding. Clin. Exp. Gastroenterol. 2016; 9: 337–43.

bleeding,[190] have lower rates of hemostasis (as low as 40 percent), with higher recurrent bleeding rates (over 50 percent within 1 month), with high 3 month mortality.[191] [192] Continued bleeding that is not controlled by conventional techniques, or recurrent bleeding from the same lesion may be treated by repeated attempts at endoscopic hemostasis, interventional radiology hemostasis (IRH) with guided transarterial embolization (TAE), or surgery.[193] According to the applicant, a recent systematic review found minimally invasive options like TAE had re-bleeding rates that were higher than those from surgery with no significant difference in mortality.[194] According to the applicant, patients who are not surgical candidates have very few options for ''rescue'' when conventional hemostasis techniques fail.

The applicant asserted that, in addition to increased morbidity and mortality, the financial impact of failure to achieve hemostasis is considerable. Based on a retrospective claims analysis by the applicant of the 2012 MedPAR file and the Provider of Services file, 13,501 cases were identified which showed all-cause mortality for patients requiring more than 1 endoscopy (6%), IRH (9%), or surgery (14%) was significantly higher than for patients requiring only 1 endoscopy (3%).[195] The median hospital costs for these patients were considerable, with costs for patients requiring over 1 endoscopy of $20,055, for patients requiring IRH of $34,730, and for patients requiring surgery of $47,589. According to the applicant, Hemospray is an alternative to IRH and surgery and the applicant asserts it would avoid the costs associated with these procedures.

With respect to the newness criterion, the applicant for Hemospray received FDA *de novo* approval on May 7, 2018. The applicant stated revisions to the instructions for use were required by the FDA and therefore the device was not commercially available until July 1, 2018. The FDA has classified Hemospray as a Class II device for intraluminal gastrointestinal use. The applicant stated that currently, there is no ICD–10–PCS code to uniquely identify procedures involving the administration of Hemospray. We note the applicant submitted a request for approval for a unique ICD–10–PCS code for the administration of Hemospray beginning in FY 2021. The applicant stated this technology does not have a HCPCS code.

According to information submitted by the applicant, Cook Medical is voluntarily recalling Hemospray® Endoscopic Hemostat due to complaints received that the handle and/or activation knob on the device in some cases has cracked or broken when the device is activated and in some cases has caused the carbon dioxide cartridge to exit the handle. The applicant stated that Cook Medical has received 1 report of a superficial laceration to the user's hand that required basic first aid; however, there have been no reports of laceration, infection, or permanent impairment of a body structure to users or to patients due to the carbon dioxide cartridge exiting the handle. The applicant stated that Cook Medical has initiated an investigation and will determine the appropriate corrective action(s) to prevent recurrence of this issue. According to the applicant, although the recall does restrict availability of the device, they wish to continue their application for new technology add-on payment as they believe the use of Hemospray significantly improves clinical outcomes for certain patient populations compared to currently available treatments.

As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposed of new technology add-on payments. The applicant identified three treatment options currently available for the treatment of bleeding of the gastrointestinal system, which were thermal modalities, injection needles, and mechanical modalities. The applicant stated that thermal modalities are those endoscopic methods that treat gastrointestinal hemorrhage by means of bipolar electrocautery, hemostatic graspers, and argon plasma coagulation. These devices generate heat resulting in edema, coagulation of tissue protein, and contraction of vessels and indirect activation of the coagulation cascade. The applicant stated that injection needles treat gastrointestinal hemorrhage through the injection of various materials including epinephrine, saline, histocryl, ethanolamine, and ethanol. This method achieves hemostasis by both mechanical tamponade and cytochemical mechanisms.[196] The applicant stated that mechanical modalities including hemostatic endoclips, detachable loop ligators and multi-band ligators control gastrointestinal hemorrhage by applying mechanical pressure to the bleeding site. The applicant claimed these treatment options (thermal modalities, injection needles, and mechanical modalities) are insufficient in achieving hemostasis as evidenced by rates of failed hemostasis of 8 to 15 percent.[197] The applicant stated that all the current treatments result in injury to the tissue, which in some cases can result in a worsening of the severity of the bleeding or perforation. Furthermore, it stated that with the exception of argon plasma coagulation, the current hemostatic modalities require precise targeting of the source of the bleed, which may limit their utility when diffuse or non-precise bleeding occurs. According to the applicant, the primary benefit of all endoscopic hemostasis procedures, including Hemospray, is the achievement of hemostasis without conversion to interventional radiology or surgery, both of which carry higher risk of mortality and morbidity.[198]

With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, the application asserted that Hemospray is a novel device in which the mechanism of action differs from alternative treatments by creating a diffuse mechanical barrier over the site of bleeding with a non-thermal, non-traumatic, noncontact modality.

With respect to the second criterion, whether a product is assigned to the same or different MS–DRG, the applicant did not specifically comment. The applicant stated that cases involving the use of Hemospray would span a wide variety of MS–DRGs, but

[190] Heller SJ, Tokar JL, Nguyen MT, et al. Management of bleeding GI tumors. Gastrointest Endosc 2010;72:817–24.

[191] Kim YI, Choi IJ, Cho SJ, et al. Outcome of endoscopic therapy for cancer bleeding in patients with unresectable gastric cancer. J Gastroenterol Hepatol 2013;28:1489–95.

[192] Roberts SE, Button LA, Williams JG. Prognosis following upper gastrointestinal bleeding. PLoS One 2012;7:e49507.

[193] Lau JY, Sung JJ, Lam YH, et al. Endoscopic retreatment compared with surgery in patients with recurrent bleeding after initial endoscopic control of bleeding ulcers. N Engl J Med 1999; 340: 751–756.

[194] Beggs AD, Dilworth MP, Powell SL, et al. A systematic review of transarterial embolization versus emergency surgery in treatment of major nonvariceal upper gastrointestinal bleeding. Clin Exp Gastroenterol 2014; 7: 93–104.

[195] Roy A, Kim M, Hawes R, Varadarajulu S. The clinical and cost implications of failed endoscopic hemostasis in gastroduodenal ulcer bleeding. UEG Journal 2017; 5(3): 359–364.

[196] ASGE, The role of endoscopy in the management of acute non-variceal upper GI bleeding, Gastrointestinal Endoscopy. 2012; 75(6): 1132–1138.

[197] Lau J, Barkun A, Fan D, Kuipers E, Yang Y, Chan F. Challenges in the management of acute peptic ulcer bleeding. Lancet 2013; 381: 2033–43.

[198] Beggs AD, Dilworth MP, Powell SL, et al. A systematic review of transarterial embolization versus emergency surgery in treatment of major nonvariceal upper gastrointestinal bleeding. Clin Exp Gastroenterol 2014; 7: 93–104.

that the technology would most likely be used for cases in MS–DRGs 377, 378, and 379 (G.I. Hemorrhage with MCC, with CC, and without CC/MCC, respectively). We believe that cases involving the use of the technology would be assigned to the same MS–DRG as cases involving the current standard of care treatments.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, we note that the applicant also did not comment specifically on this criterion. However, we believe that this technology would be used to treat the same or similar type of disease and the same or similar patient population as the current standard of care treatments.

Based on the applicant's statements as summarized previously, the applicant believes that Hemospray is not substantially similar to other currently available therapies and/or technologies and meets the ''newness'' criterion. However, we are concerned that the mechanism of action of Hemospray may be similar to existing endoscopic hemostatic treatments. Specifically, we note that as described in literature provided by the applicant, technologies such as Ankaferd Bloodstopper and EndoClot Polysaccharide Hemostatic System appear to utilize a similar mechanism of action as Hemospray to achieve hemostasis.[199] Based on the literature provided by the applicant, EndoClot, a device developed in California, USA, ''. . . consists of absorbable modified polymer . . . [which is] biocompatible, non-pyogenic, and starch-derived compound that rapidly absorbs water from serum and concentrates platelets, red blood cells, and coagulation proteins at the bleeding site to accelerate the clotting cascade.'' [200] EndoClot received 510(k) premarket notification January 18, 2017 and is indicated by the FDA to assist the delivery of a powdered hemostatic agent to the treatment site in endoscopic surgeries. Therefore, we are concerned with the similarity of this mechanism of action. Moreover, as previously noted, the applicant asserted generally it did not meet the substantial similarity criteria, but did not specifically address the second and third substantial similarity criteria. We believe that cases involving the use of the Hemospray would be assigned to the same MS–DRG as cases involving the current standard-of-care treatments and that the technology would be used to treat the same or similar type of disease and the same or similar patient population as the current standard-of-care treatments.

We are inviting public comments on whether Hemospray is substantially similar to other currently available therapies and/or technologies and whether this technology meets the newness criterion.

With regard to the cost criterion, the applicant provided the following analysis to demonstrate the technology meets the cost criterion. The applicant asserted patients who would use Hemospray are identified by using a combination of one ICD–10–PCS procedure code and one ICD–10–CM diagnosis code. The applicant provided a list of 39 ICD–10–PCS procedure codes that included 21 Non O.R. digestive system procedures and 18 Extensive O.R. digestive system procedures. The applicant provided a list of 32 ICD–10–CM diagnosis codes that included 29 principal diagnoses in MS–DRGs 377, 378, and 379 (G.I. Hemorrhage with MCC, with CC, and without CC/MCC, respectively) and 3 principal diagnoses in MDC 06 (Diseases and Disorders of the Digestive System) across 10 MS–DRG classifications. The applicant extracted claims from the FY 2018 MedPAR final rule dataset based on the presence of one procedure and one diagnosis code in the list provided. The applicant stated MS–DRGs 377, 378, and 379 made up 3 of the top 4 MS–DRGs by volume and about 64 percent of cases were grouped to these 3 MS–DRGs. The applicant stated consequently they limited their analysis to the cases assigned to MS–DRGs 377, 378, and 379 and those claims that would be used for IPPS rate setting. The applicant identified a total of 40,012 cases.

The applicant first calculated a case weighted threshold of $46,568 based upon the dollar threshold for each MS–DRG grouping and the proportion of cases in each MS–DRG. The applicant then calculated the average charge per case. The applicant stated Hemospray may not replace other therapies occurring during an inpatient stay and therefore chose to not remove charges for the prior technology or technology being replaced. Next the applicant calculated the average standardized charge per case using the FY 2018 IPPS Final Rule Impact file. The 2-year inflation factor of 11.1% (1.11100) was obtained from the FY 2020 IPPS/LTCH PPS final rule and applied to the average standardized charge per case. To determine the charges for Hemospray, the applicant used the inverse of the FY 2020 IPPS/LTCH PPS final rule supplies and equipment national average CCR of 0.299, based on an assumption that hospitals would use the inverse of the national average CCR for supplies and equipment to mark-up charges, and therefore assumed an average charge for Hemospray of $8,361.20. The applicant calculated the final inflated average case-weighted standardized charge per case by adding the charges for the new technology to the inflated average standardized charge per case. The applicant determined a final inflated average case-weighted standardized charge per case of $60,193, which exceeds the average case-weighted threshold amount of $46,568.

We are inviting public comments on whether Hemospray meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that Hemospray represents a substantial clinical improvement over existing technologies. According to the applicant, Hemospray is a topically applied mineral powder that offers a novel primary treatment option for endoscopic bleeding management, serves as an option for patients who fail conventional endoscopic treatments, and serves as an alternative to interventional radiology hemostasis (IRH) and surgery. Broadly, the applicant outlined two treatment areas in which it asserted Hemospray would provide a substantial clinical improvement: (1) As a primary treatment or a rescue treatment after the failure of a conventional method, and (2) in the use for the treatment of malignant lesions.

The applicant provided eight articles specifically for the purpose of addressing the substantial clinical improvement criterion. Three articles are systematic reviews, three are prospective studies, and two are retrospective studies.

The first article provided by the applicant was a prospective single armed multicenter phase two safety and efficacy study performed in France.[201] From March 2013 to January 2015, 64 endoscopists in 20 centers enrolled 202 patients in the study in which Hemospray was used as either a first line treatment (46.5%) or salvage therapy (53.5%) following the unsuccessful treatment with another method. The indication for Hemospray as a first-line therapy or salvage therapy

[199] Barkun, A., Moosavi, S., & Martel, M. (2013). Topical hemostatic agents: A systematic review with particular emphasis on endoscopic application in GI bleeding. Gastrointestinal Endoscopy, 77(5), 692–700.

[200] Ibid.

[201] Haddara S, Jacques J, Lecleire S et al. A novel hemostatic powder for upper gastrointestinal bleeding: A multicenter study (the GRAPHE registry). Endoscopy 2016; 48: 1084–95.

was at the discretion of the endoscopist. Of the 202 patients the mean age was 68.9, 69.3 percent were male, and all patients were classified into four primary etiologic groups: Ulcers (37.1%), malignant lesions (30.2%), post-endoscopic bleeding (17.3%), and other (15.3%). Patients were further classified by the American Society of Anesthesiologist (ASA) physical status scores with 4.5 percent as a normal healthy patient, 24.3 percent as a patient with mild systemic disease, 46 percent as a patient with severe systemic disease, 22.8 percent as a patient with severe systemic disease that is a constant threat to life, and 2.5 percent as a moribund patient who is not expected to survive without an operation.[202] [203] Immediate hemostasis was achieved in 96.5 percent across all patients; among treatment subtypes immediate hemostasis was achieved in 96.8 percent of first-line treated patients and 96.3 percent of salvage therapy patients. At day 30 the overall rebleeding was 33.5 percent of 185 patients with cumulative incidences of 41.4 percent for ulcers, 37.7 percent for malignant lesions, 17.6 percent for post-endoscopic bleedings, and 25 percent for others. When Hemospray was used as a first-line treatment, rebleeding at day 30 occurred in 26.5 percent (22/83) of overall lesions, 30.8 percent of ulcers, 33.3 percent of malignant lesions, 13.6 percent of post-endoscopic bleedings, and 22.2 percent of other. When Hemospray was used as a salvage therapy, rebleeding at day 30 occurred in 39.2 percent (40/102) of overall lesions, 43.9 percent of ulcers, 50.0 percent of malignant lesions, 25.0 percent of post-endoscopic bleedings, and 26.3 percent for others. According to the article, the favorable hemostatic results seen from Hemospray are due to its threefold mechanism of action: Formation of a mechanical barrier; concentration of clotting factors at the bleeding site; and enhancement of clot formation.[204] No severe adverse events were noted, however the authors note the potential for pain exists due to the use of carbon dioxide. Lastly, the authors stated that while Hemospray was found to reduce the need for radiological embolization and surgery as salvage therapies, it was not found to be better than other hemostatic methods in terms of preventing rebleeding of ulcers.

A second article provided by the applicant contained a systematic review of published Hemospray case data summarizing 17 human and 2 animal studies.[205] The authors do not provide the total number of articles reviewed but do provide search terms and engines used to conduct the review. The studies included in this review included 6 case reports and 13 case series taking place in North America, Europe, Hong Kong, and Egypt up until August 2014. A total of 234 cases were identified of which 28.2 percent involved gastric bleeding, 6.4 percent esophageal bleeding, 26.5 percent duodenal bleeding, 3.85 percent bleeding of the gastroesophageal junction, and 11 percent bleeding of the lower gastrointestinal tract. (We note it is unclear what form of bleeding the remaining 24.1 percent of cases addressed.) The mean size of the bleeding source was 37.4 mm ranging from 8 mm to 350 mm. Hemospray was used as a primary and sole treatment in 83 percent of cases while 17 percent of cases used Hemospray as a follow-up treatment. Hemospray achieved hemostasis in 88.5 percent of all reviewed cases. Within the 72-hour post-treatment period, rebleeding occurred in 16.2 percent of patients and 27.3 percent of animal models. The authors acknowledge the potential for rare adverse events such as embolism, intestinal obstruction, and allergic reaction, but state no procedure related adverse events were associated with Hemospray.[206]

The applicant provided a third article consisting of an abstract from another systematic review article.[207] The abstract purports to cover a review of prospective, retrospective, and randomized control trials evaluating Hemospray as a rescue therapy. Eighty-five articles were initially identified and 23 were selected for review. Of those, 5 studies were selected which met the inclusion criteria of the analysis. The median age of patients was 69, 68 percent were male. The abstract concludes that when used as a rescue therapy after the failure of conventional endoscopic modalities, in nonvariceal gastrointestinal bleeding, Hemospray seems to have significantly higher rates of immediate hemostasis.

A fourth article provided by the applicant described a single-arm retrospective analytical study of 261 enrolled patients conducted at 21 hospitals in Spain.[208] The mean age was 67 years old, 69 percent of patients were male, and the overall technical success, defined as correct assembled and delivery of Hemospray to a bleeding lesion, was 97.7 percent (95.1%–99.2%). The most common causes of bleeding in patients were peptic ulcer (28%), malignancy (18.4%), therapeutic endoscopy-related (17.6%), and surgical anastomosis (8.8%). Overall, 93.5 percent (89.5%–96%) of procedures achieved hemostasis. Recurrent bleeding, defined as (1) a new episode of bleeding symptoms, (2) a decrease in hemoglobin of >2 g/dL within 48 hours of an index endoscopy or >3g/dL in 24 hours, or (3) direct visualization of active bleeding at the previously treated lesion on repeat endoscopy, had a cumulative incidence at 3 and 30 days of 16.1 percent (11.9%–21%) and 22.9 percent (17.8%–28.3%) respectively. The overall risk of Hemospray failure at 3 and 30 days was 21.1 percent (16.4%–26.2%) and 27.4 percent (22.1%–32.9%) respectively with no statistically significant differences (p=0.07) between causes at 30 days (for example peptic ulcer, malignancy, anastomosis, therapeutic endoscopy-related, and other causes). With the use of multivariate analysis spurting bleeding vs. nonspurting bleeding (subdistribution hazard ratio [sHR] 1.97 (1.24–3.13)), hypotension vs. normotensive (sHR 2.14 (1.22–3.75)), and the use of vasoactive drugs (sHR 1.80 (1.10–2.95)) were independently associated with Hemospray failure. The overall 30-day survival was 81.9 percent (76.5%–86.1%) with 46 patients dying during follow-up and 22 experiencing bleeding related deaths; twenty patients (7.6%) with intraprocedural hemostasis died before day 30. The authors indicated the majority of Hemospray failures occurred within the first 3 days and the rate of immediate hemostasis was similar to literature reports of intraprocedural success rates of over 90 percent. The authors stated that the hemostatic powder of Hemospray is eliminated from the GI tract as early as 24 hours after use, which could explain the wide ranging recurrent bleeding percentage. The authors reported that

[202] Ibid.

[203] ASA House of Delegates/Executive Committee. (2014, October 15). *ASA Physical Status Classification System.* Retrieved from American Society of Anesthesiologists: *https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system.*

[204] Haddara S, Jacques J, Lecleire S et al. A novel hemostatic powder for upper gastrointestinal bleeding: A multicenter study (the GRAPHE registry). Endoscopy 2016; 48: 1084–95.

[205] Changela K, Papafragkakis H, Ofori E, et al. Hemostatic powder spray: A new method for managing gastrointestinal bleeding. Ther Adv Gastroenterol 2015; 8(3): 125–135.

[206] Ibid.

[207] Moole, V., Chatterjee, T., Saca, D., Uppu, A., Poosala, A., & Duvvuri, A. A Systematic review and meta-analysis: Analyzing the efficacy of hemostatic nanopowder (TC–325) as rescue therapy in patients with nonvariceal upper gastrointestinal bleeding. Gastroenterology 2019; 156(6), S–741.

[208] Rodriguez de Santiago E, Burgos-Santamaria D, Perez-Carazo L, et al. Hemostatic spray TC–325 for GI bleeding in a nationwide study: Survival analysis and predictors of failure via competing risks analysis. Gastrointest Endosc 2019; 90(4), 581–590.

importantly, adverse events are rare, but cases of abdominal distension, visceral perforation, transient biliary obstruction, and splenic infarct have been reported; one patient involved in this study experienced an esophageal perforation without a definitive causal relationship.

A fifth article provided by the applicant described a single-arm multicenter prospective registry involving 314 patients in Europe which collected data on days 0, 1, 3, 7, 14, and 30 after endotherapy with Hemospray.[209] The outcomes of interest in this study were immediate endoscopic hemostasis (observed cessation of bleeding within 5 minutes post Hemospray application) with secondary outcomes of rebleeding immediately following treatment and during follow-up, 7 and 30 day all-cause mortality, and adverse events. The sample was 74 percent male with a median age of 71 with the most common pathologies of peptic ulcer (53%), malignancy (16%), post-endoscopic bleeding (16%), bleeding from severe inflammation (11%), esophageal variceal bleeding (2.5%), and cases with no obvious cause (1.6%). The median baseline Blatchford score (BS) and RS were 11 and 7 respectively. The BS ranges from 0 to 23 with higher scores indicating increasing risk for required endoscopic intervention and is based upon the blood urea nitrogen, hemoglobin, systolic blood pressure, pulse, presence of melena, syncope, hepatic disease, and/or cardiac failure.[210] The RS ranges from 0 to 11 with higher scores indicating worse potential outcomes and is based upon age, presence of shock, comorbidity, diagnosis, and endoscopic stigmata of recent hemorrhage.[211] Immediate hemostasis was achieved in 89.5 percent of patients following the use of Hemospray; only the BS was found to have a positive correlation with treatment failure in multivariate analysis (OR 1.21 (1.10–1.34)). Rebleeding occurred in 10.3 percent of patients who achieved immediate hemostasis again with only the BS having a positive correlation with rebleeding (OR: 1.13 (1.03–1.25)). At 30 days the all-cause mortality was 20.1 percent with 78 percent of these patients having achieved immediate endoscopic hemostasis and a cause of death resulting from the progression of other comorbidities. A subgroup analysis of treatment type (monotherapy, combination therapy, and rescue therapy groups) was performed showing no statistically significant difference in immediate hemostasis across groups (92.4 percent, 88.7 percent, and 85.5 percent respectively). Higher all-cause mortality rates at 30 days were highest in the monotherapy group (25.4%, p=0.04) as compared to all other groups. According to the authors, in comparison to major recent studies they were able to show lower rebleeding rates overall and in all subgroups despite the high-risk population.[212] The authors further note limitations in that the inclusion of patients was nonconsecutive and at the discretion of the endoscopist, at the time of the endoscopy, which allows for the potential introduction of selection bias, which may have affected these study results.

The fifth article also described the utility of Hemospray in the treatment of malignant lesions. According to the applicant, malignant lesions pose a significant clinical challenge as successful hemostasis rates are as low as 40 percent with high recurrent bleeding over 50 percent within 1 month following standard treatments.[213] [214] The applicant added that bleeding from tumors is often diffuse and consists of friable mucosa decreasing the utility of traditional treatments (for example, ligation, cautery). From the fifth article, the applicant noted that 50 patients were treated for malignant bleeding with an overall immediate hemostasis in 94 percent of patients.[215] Of the 50 patients, 33 were treated with Hemospray alone, 11 were treated with Hemospray as the final treatment, and 4 were treated with Hemospray as a rescue therapy of which 100 percent, 84.6 percent and 75 percent experienced immediate hemostasis respectively.[216] Similarly, from the first discussed article, the applicant noted that among malignant bleeding patients, 95.1 percent achieved immediate hemostasis with lower rebleeding rates at 8 days when Hemospray was used as a primary treatment as compared to when used as a rescue therapy (17.1 percent vs. 46.7 percent respectively).[217] The applicant concluded that Hemospray may provide an advantage as a primary treatment to patients with malignant bleeding.

A sixth article provided by the applicant consisted of a systematic review from January 1950 to August 2014 concerning all available powdered topical hemostatic agents.[218] Of an initial 3,799 articles, 105 were initially reviewed and after excluding nonendoscopic data, review articles, in vitro studies, and animal models 61 articles were ultimately included in the study. Three primary hemostatic agents were identified in this review, the Ankaferd Blood Stopper (ABS), Hemospray, and EndoClot. The applicant noted the authors of this article identified 131 high risk patients treated with Hemospray, of which 28 had tumor bleeding. According to the applicant, all 28 patients achieved immediate hemostasis with 25 percent experiencing rebleeding at 7-day follow-up. The overall immediate hemostasis in this particular study was 91.6 percent and 7-day rebleeding 25.8 percent among high-risk rebleeding patients.[219]

The applicant provided a seventh article which consisted of a journal pre-proof article detailing a 1:1 randomized control trial of 20 patients treated with Hemospray versus the standard of care (for example, thermal and injection therapies) in the treatment of malignant gastrointestinal bleeding.[220] The goals of this pilot study were to determine the feasibility of a definitive trial. The primary outcome of the study was immediate hemostasis (absence of bleeding after 3 minutes) with secondary outcomes of recurrent bleeding at days 1, 3, 30, 90, and 180 and adverse events at days 1, 30, and

[209] Alzoubaidi D, Hussein M, Rusu R, et al. Outcomes from an international multicenter registry of patients with acute gastrointestinal bleeding undergoing endoscopic treatment with Hemospray. Digestive Endoscopy 2019.

[210] Saltzman, J. (2019, October). Approach to acute upper gastrointestinal bleeding in adults. (M. Feldman, Editor) Retrieved from UpToDate: *https://www.uptodate.com/contents/approach-to-acute-upper-gastrointestinal-bleeding-in-adults.*

[211] Ibid.

[212] Alzoubaidi D, Hussein M, Rusu R, et al. Outcomes from an international multicenter registry of patients with acute gastrointestinal bleeding undergoing endoscopic treatment with Hemospray. Digestive Endoscopy 2019.

[213] Kim YI, Choi IJ, Cho SJ, et al. Outcome of endoscopic therapy for cancer bleeding in patients with unresectable gastric cancer. J Gastroenterol Hepatol 2013;28:1489–95.

[214] Roberts SE, Button LA, Williams JG. Prognosis following upper gastrointestinal bleeding. PLoS One 2012;7:e49507.

[215] Alzoubaidi D, Hussein M, Rusu R, et al. Outcomes from an international multicenter registry of patients with acute gastrointestinal bleeding undergoing endoscopic treatment with Hemospray. Digestive Endoscopy 2019.

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[217] Haddara S, Jacques J, Lecleire S et al. A novel hemostatic powder for upper gastrointestinal bleeding: A multicenter study (the GRAPHE registry). Endoscopy 2016; 48: 1084–95.

[218] Chen Y-I, Barkun A. Hemostatic powders in gastrointestinal bleeding, a systematic review. Gastrointest Endoscopy Clin N Am 2015; 25: 535–552.

[219] Ibid.

[220] Chen Y-I, Wyse J, Lu Y, Martel M, Barkun AN, TC–325 hemostatic powder versus current standard of care in managing malignant GI bleeding: A pilot randomized clinical trial. Gastrointestinal Endoscopy (2019), doi: *https://doi.org/10.1016/j.gie.2019.08.005.*

180. The mean age of patients was 67.2, 75 percent were male, and on average patients presented with 2.9 ± 1.7 comorbidities. All patients had active bleeding at endoscopy and the majority of patients had an ASA score of 2 (45%) or 3 (40%). Immediate hemostasis was achieved in 90 percent of Hemospray patients and 40 percent of standard of care patients (5 injection alone, 3 thermal, 1 injection with clips, and 1 unknown). Of those patients in the control group, 83.3 percent crossed over to the Hemospray treatment. One patient died while being treated with Hemospray from exsanguination; post-mortem examination demonstrated that bleeding was caused by rupture of a malignant inferior mesenteric artery aneurysm. Overall, 86.7 percent of patients treated with Hemospray initially or as crossover treatment achieved hemostasis. Recurrent bleeding was lower in the Hemospray group (20%) as compared to the control group (60%) at 180 days. Forty percent of the treated group received blood transfusions as compared to 70 percent of the control group. The overall length of stay was 14.6 days among treated patients as compared to 9.4 in the control group. Mortality at 180 days was 80 percent in both the treated and control groups. The authors noted the potential for operator bias in the use of Hemospray prior to switching to another method when persistent bleeding exists. Lastly, the authors noted that while they did not occur during this study, there are concerns around the risks of perforation, obstruction, and systemic embolization with the use of Hemospray.

An eighth article provided by the applicant described a single-arm multicenter retrospective study from 2011 to 2016 involving 88 patients who bled as a result of either a primary GI tumor or metastases to the GI tract.[221] In this study the authors define immediate hemostasis as no further bleeding at least one minute after treatment with Hemospray and recurrent bleeding was suspected if one of seven criteria were met: (1) Hematemesis or bloody nasogastric tube >6 hours after endoscopy; (2) melena after normalization of stool color; (3) hematochezia after normalization of stool color or melena; (4) development of tachycardia or hypotension after >1 hour of vital sign stability without other cause; (5) decrease in hemoglobin level greater than or equal to 3 hours apart; (6) tachycardia or hypotension that does not resolve within 8 hours after index endoscopy; or (7) persistent decreasing hemoglobin of >3 g/dL in 24 hours associated with melena or hematochezia). The sample for this study consisted of 88 patients (with a mean age of 65 years old and 70.5 percent male) of which 33.3 percent possessed no co-morbid illness, and 25 percent were on current antiplatelet/anticoagulant medication. The mean BS was 8.7 plus or minus 3.7 with a range from 0 to 18. Overall, 72.7 percent of patients had a stage 4 adenocarcinoma, squamous cell carcinoma, or lymphoma. Immediate hemostasis was achieved in 97.7 percent of patients. Recurrent bleeding occurred among 13 of 86 (15%) and 1 of 53 (1.9%) at 3 and 30 days, respectively. A total of 25 patients (28.4%) died during the 30-day follow up period. Overall, 27.3 percent of patients re-bled within 30 days after treatment of which half were within 3 days. Using multivariate analysis, the authors found patients with good performance status, no end-stage cancer, or receiving any combination of definitive hemostasis treatment modalities had significantly greater survival. The authors acknowledged the recurrent bleeding rate post Hemospray treatment at 30 days of 38 percent is comparable with that seen in sole conventional hemostatic techniques and state this implies that Hemospray does not differ from conventional techniques and remains unsatisfactory.

Ultimately, the applicant concluded nonvariceal gastrointestinal bleeding is associated with significant morbidity and mortality in older patients with multiple co-morbid conditions. Inability to achieve hemostasis and early rebleeding are associated with increased cost and greater resource utilization. According to the applicant, patients with bleeding from malignant lesions have few options that can provide immediate hemostasis without further disrupting fragile mucosal tissue and worsening the active bleed. The applicant asserted Hemospray is an effective agent that provides immediate hemostasis in patients with GI bleeding as part of multimodality treatment, as well as when used to rescue patients who have failed more conventional endoscopic modalities. Furthermore the applicant stated that in patients with malignant bleeding in the GI tract, Hemospray provides a high rate of immediate hemostasis and fewer recurrent bleeding episodes, which in combination with definitive cancer treatment may lead to improvements in long term survival. Lastly, the applicant asserted Hemospray is an important new technology that permits immediate and long-term hemostasis in GI bleeding cases where standard of care treatment with clip ligation or cautery are not effective.

We note that the majority of studies provided lack a comparator when assessing the effectiveness of Hemospray. Three of the articles provided are systematic reviews of the literature. While we find these articles helpful in establishing a background for the use of Hemospray, we are concerned that they may not provide strong evidence of substantial clinical improvement. Four studies appear to be single-armed studies assessing the efficacy of Hemospray in the patient setting. In all of these articles, comparisons are made between Hemospray and standard of care treatments; however, without the ability to control for factors such as study design, patient characteristics, etc., it is difficult to determine if any differences seen result from Hemospray or confounding variables. Furthermore, within the retrospective and prospective studies lacking a control subset, some level of selection bias appears to potentially be introduced in that providers may be allowed to select the manner and order in which patients are treated, thereby potentially influencing outcomes seen in these studies.

Additionally, one randomized control trial provided by the applicant appears to be in the process of peer-review and is not yet published. Furthermore, this article is written as a feasibility study for a potentially larger randomized control trial and contains a sample of only 20 patients. This small sample size leaves us concerned that the results are not representative of any larger population. Lastly, as described we are concerned the control group can receive one of multiple treatments which lack a clear designation methodology beyond physician choice. For instance, 50 percent of the control patients received injection therapy alone, which according to the literature provided by the applicant is not an acceptable treatment for endoscopic bleeding. Accordingly, it is not clear whether performance seen in the treated group as compared to the control group is due to Hemospray itself or due to confounding factors.

Third, we are concerned with the samples chosen in many of the studies presented. Firstly, the Medicare population is a diverse group of men and women. Many of the samples provided by the applicant are overwhelmingly male. Secondly, many

[221] Pittayanon R, Rerknimitr R, Barkun A. Prognostic factors affecting outcomes in patients with malignana GI bleeding treated with a novel endoscopically delivered hemostatic powder. Gastrointest Endosc 2018; 87:991–1002.

of the studies provided were performed in European and other settings outside of the United States. We are therefore concerned that the samples chosen within the literature provided may not represent the Medicare population.

Lastly, we are concerned about the potential for adverse events resulting from Hemospray. It is unclear from the literature provided by the applicant what the likelihood of these events is and whether or not an evaluation for the safety of Hemospray was performed. About one-third of the articles submitted specifically addressed adverse events with Hemospray. However, the evaluation of adverse events was limited and most of the patients in the studies died of disease progression. A few of the provided articles mention the potential for severe adverse reactions (for example, abdominal distension, visceral perforation, biliary obstruction, splenic infarct). Specifically, one article [222] recorded adverse events related to Hemospray, including abdominal distention and esophageal perforation.

We are inviting public comments on whether Hemospray meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for Hemospray or at the New Technology Town Hall meeting.

h. IMFINZI® (Durvalumab)

AstraZeneca PLC submitted an application for new technology add-on payments for IMFINZI® for FY 2021. According to the applicant, IMFINZI® is a selective, high-affinity, human IgG1 monoclonal antibody (mAb) that blocks programmed death-ligand 1 (PD–L1) binding to programmed cell death-1 and CD80 without antibody-dependent cell-mediated cytotoxicity.[223] IMFINZI® has multiple indications but is applying for new technology add-on payments for IMFINZI® in combination with etoposide and either carboplatin or cisplatin for the first-line treatment of patients with extensive-stage small cell lung cancer (ES–SCLC). IMFINZI® for the first-line treatment of patients with ES–SCLC is not yet approved by the FDA.

According to the applicant, the FDA initially approved IMFINZI® on May 1, 2017 for the indicated treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or who have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum containing chemotherapy. According to the applicant, this indication received accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.[224]

The FDA subsequently approved IMFINZI® on February 16, 2018 for a second indication, treatment of patients with unresectable, Stage III non-small cell lung cancer (NSCLC) whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy.

Small cell lung cancer (SCLC) is considered a rare disease, with approximately 30,000 new cases diagnosed each year, compared to 200,000 cases of NSCLC.[225] SCLC was among the cancers identified by the National Cancer Institute for which to develop plans for research under the Recalcitrant Cancer Research Act of 2012 which supports research for cancers having a 5-year relative survival rate of less than 20 percent and estimated to cause approximately 30,000 deaths per year in the U.S.[226] SCLC is a rapidly progressive disease with poor prognosis and limited treatment options. The overall 5-year survival rate (early and late stage) is 6 percent, representing an ongoing significant unmet need.[227] The majority (75 percent) of patients are diagnosed in the late/metastatic stage described as ES–SCLC and are considered incurable, with a median overall survival of 9–11 months with standard of care (SOC).[228] [229] The median overall survival for ES–SCLC has remained the same for the past 20 years with essentially no improvements or new therapies in 20 years.[230] According to the applicant, the current SOC for first line (1L) treatment of ES–SCLC is systemic therapy with standard doublet chemotherapy with platinum plus etoposide, administered for 4–6 cycles following diagnosis. Although ES–SCLC is highly sensitive to platinum/etoposide in the 1L setting with response rates of 50–60 percent, the majority of patients will relapse within the first year of treatment, with a median progression free survival (PFS) of 4–6 months.[231] The applicant also asserts that overall, responses to SOC are short-lived and long-term outcomes remain poor.

The applicant states that extensive stage small cell lung cancer is the most rapidly progressive lung cancer, with growth of metastases that can be extremely fast, with doubling times as low as three to four days observed in one patient.[232] The applicant further states that diagnosis often occurs at later stages and SCLC patients may be sicker at the time of diagnosis, presenting with other comorbidities.[233] [234] For these reasons, the applicant asserts that a significant number of patients present and are diagnosed in the hospital inpatient setting. According to the applicant, ES–SCLC is very responsive to chemotherapy treatment, with response rates to platinum/etoposide ranging from 44 percent to 78 percent,[235] and given the severity of symptoms, it is recommended to initiate treatment within two weeks of

[222] Rodriguez de Santiago E, Burgos-Santamaria D, Perez-Carazo L, et al. Hemostatic spray TC–325 for GI bleeding in a nationwide study: Survival analysis and predictors of failure via competing risks analysis. Gastrointest Endosc 2019; 90(4), 581–590.

[223] IMFINZI® (durvalumab) [Prescribing Information]. Wilmington, DE; AstraZeneca Pharmaceuticals LP, 2019.

[224] Ibid.

[225] Noone, A.M., Howlader, N., Krapcho, M., Miller, D., Brest, A., Yu, M., Ruhl, J., Tatalovich, Z., Mariotto, A., Lewis, D.R., Chen, H.S., Feuer, E.J., Cronin, K.A. (eds). SEER Cancer Statistics Review, 1975–2015, National Cancer Institute, Bethesda, MD, *https://seer.cancer.gov/csr/1975_2015/*, based on November 2017 SEER data submission, posted to the SEER website, April 2018.

[226] Accessed October 16, 2018 3. National Cancer Institute. NCI Dictionary of Cancer Terms—small cell lung cancer; Available at *https://www.cancer.gov/about-nci/legislative/recent-public-laws#recalcitrant-cancer-research-act-of-2012-pl-112-239-s-amdt-3180-to-s-3254hr-4310-112th-congress*.

[227] *https://www.cancer.net/cancer-types/lung-cancer-small-cell/statistics*.

[228] Sabari, J.K., Lok, B.H., Laird, J.H., et al., ''Unravelling the biology of SCLC: Implications for therapy,'' *Nature Reviews Clinical Oncology,* 2017, 14(9), pp. 549–561.

[229] Farago, A.F., Keane F.K., ''Current standards for clinical management of small cell lung cancer,'' *Translational Lung Cancer Research,* 2018, 7, pp. 69–79.

[230] Ibid.

[231] Hurwitz, J.L., McCoy, F., Scullin, P., et al., ''New advances in the second-line treatment of small cell lung cancer,'' *Oncologist,* 2009, 14(10), pp. 986–994.

[232] Haque, N., Raza, A., McGoey, R., et al., ''Small cell lung cancer: time to diagnosis and treatment,'' *Southern Medical Journal,* 2012, 105(8), pp. 418–423.

[233] Bennett, B.M., Wells, J.R., Panter, C., et al., ''The humanistic burden of small cell lung cancer (SCLC): A systematic review of health-related quality of life (HRQoL) literature,'' *Frontiers in Pharmacology,* 2017, 8, p. 339.

[234] Aarts, M.J., Aerts, J.G., van den Borne, B.E., et al., ''Comorbidity in patients with small-cell lung cancer: trends and prognostic impact,'' *Clinical Lung Cancer,* 2015, 16(4), pp. 282–291.

[235] Farago, A.F., Keane, F.K, ''Current standards for clinical management of small cell lung cancer,'' *Translational Lung Cancer Research,* 2018, 7, pp. 69–79.

diagnosis.[236] According to the applicant, many patients have clinical response and improvement of symptoms with the initiation of platinum/etoposide, confirming the clinical observation that many SCLCs are highly sensitive to platinum/etoposide in the first-line setting.[237] The applicant suggests that based on the CASPIAN study design, as discussed further in this section, patients should receive IMFINZI® in combination with chemotherapy beginning in the first cycle. Thus, the applicant expects patients to receive a single dose of IMFINZI® while in the inpatient setting prior to discharge.

On November 29, 2019 the FDA accepted a supplemental Biologics License Application and granted Priority Review for IMFINZI® for the treatment of patients with previously untreated ES–SCLC. The FDA granted IMFINZI® orphan drug designation in ES–SCLC on July 12, 2019.[238] As previously noted, IMFINZI® for the first-line treatment of patients with ES–SCLC is not yet approved by the FDA.

The applicant states that there are no existing ICD–10–PCS codes that uniquely identify the administration of IMFINZI®. The applicant submitted a request for a unique ICD–10–PCS administration code for the March 2020 ICD–10 Coordination and Maintenance Committee Meeting.

As previously discussed, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and, therefore, would not be considered ''new'' for purposes of new technology add-on payments.

With respect to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant asserted that IMFINZI® offers a novel mechanism of action for the treatment of ES–SCLC compared to the SOC chemotherapy. The applicant states that first line SOC treatment of ES–SCLC is standard chemotherapy, including a platinum agent (typically carboplatin or cisplatin) plus etoposide.[239] The mechanism of action of platinum chemotherapy agents (including cisplatin and carboplatin) is based on the agent's ability to crosslink with the purine bases on the DNA; interfering with DNA repair mechanisms, causing DNA damage, and subsequently inducing apoptosis in cancer cells.[240] [241]

The applicant asserts that etoposide phosphate is a plant alkaloid prodrug that is converted to its active moiety, etoposide, by dephosphorylation. Further, the applicant explains etoposide causes the induction of DNA strand breaks by an interaction with DNA-topoisomerase II or the formation of free radicals, leading to cell cycle arrest, primarily at the G2 stage of the cell cycle, and cell death.[242] [243]

The applicant states IMFINZI® is a selective, high-affinity, human IgG1κ monoclonal antibody that blocks PD–L1 binding to programmed cell death-1 and CD80 without antibody-dependent cell-mediated cytotoxicity.[244] The applicant asserts that IMFINZI®, in combination with chemotherapy, demonstrated a statistically and clinically significant improvement in overall survival in a randomized Phase III study (CASPIAN), which is discussed later in this section.[245]

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant asserted that extensive stage small cell lung cancer patients are identified under category C34 (Malignant neoplasm of bronchus and lung) of the ICD–10–CM coding classification system. According to the applicant, category C34 is all encompassing and does not distinguish between the lung cancer subtypes. The applicant also states that both non-small cell lung cancer patients as well as earlier stages of small cell lung cancer (that is, limited stage) are captured under category C34, all of which have differing epidemiological considerations and treatment interventions. The applicant concluded that patients diagnosed with ES–SCLC, identified using category C34, map to MS–DRGs 180, 181, and 182 (Respiratory Neoplasms with MCC, with CC, and without CC/MCC, respectively). The applicant stated that the existing ICD–10–PCS coding system does not allow for visibility into the different MS–DRGs that ES–SCLC patients map to versus NSCLC patients, making it difficult to show that ES–SCLC patients receiving IMFINZI® would map to a unique MS–DRG from NSCLC cases, where IMFINZI® and other immuno-oncology therapies are already being used.

To further identify the patient population of interest, the applicant pulled charge level data from the Premier Hospital Database to determine which MS–DRGs these cases are mapping to, beyond relying on the broad lung cancer category C34. The applicant asserts that the Premier Hospital database is a large U.S. hospital-based, all payer database that contains discharge information from geographically diverse non-governmental, community, and teaching hospitals and health systems across both rural and urban areas. The applicant stated that this database contains data from standard hospital discharge files providing access to all procedures, diagnoses, drugs, and devices received for each patient regardless of the insurance or disease state. The applicant used charge level hospital data from the Premier Hospital Database to identify cases that used category C34 as well as carboplatin or cisplatin plus etoposide, the chemotherapy doublet specifically used for ES–SCLC patients. The applicant also looked for the use of prophylactic cranial irradiation (PCI), a type of radiation therapy used for ES–SCLC patients to address the frequent occurrence of multiple brain metastases associated with SCLC. Based on this assessment of hospital charge-level data, the applicant stated that over 60 percent of ES–SCLC patients map to MS–DRGs 180 (Respiratory Neoplasms with MCC), 181 (Respiratory Neoplasms with CC), and 164 (Major Chest Procedures with CC). We agree with the applicant that patients receiving IMFINZI® would map to the same DRGs as patients receiving standard therapy for ES–SCLC.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the

[236] Haque, N., Raza, A., McGoey, R., et al., ''Small cell lung cancer: time to diagnosis and treatment,'' *Southern Medical Journal,* 2012, 105(8), pp. 418–423.

[237] Ibid.

[238] *https://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=691319.*

[239] Farago, A.F., Keane, F.K., ''Current standards for clinical management of small cell lung cancer,'' *Translational Lung Cancer Research,* 2018, 7, pp. 69–79.

[240] Dasari, S., Tchounwou, P.B., ''Cisplatin in cancer therapy: Molecular mechanisms of action,'' *European Journal of Pharmacology,* 2014, 740, pp. 364–378.

[241] Thirumaran R, Prendergast GC, Gilman PB, ''Cytotoxic chemotherapy in clinical treatment of cancer,'' In: Prendergast, G.C., Jaffee, E.M., editors, *Cancer Immunotherapy: Immune Suppression and Tumor Growth,* USA: Elsevier Inc, 2007, pp. 101–116, *http://dx.doi.org/10.1016/B978-012372551-6/50071-7.*

[242] Ibid.

[243] Etopophos® (etoposide phosphate) [Prescribing Information]. Princeton, NJ; Bristol-Myers Squibb, 2019.

[244] Pas-Ares, L., Jiang, H., Huang, Y., et al., A Phase III Randomized Study of First-Line Durvalumab±Tremelumimab+Platinum-based Chemotherapy (EP) vs. EP Alone in Extensive-Stage Disease Small Cell Lung Cancer (ED–SCLC):CASPIAN [Poster]. Presented at: the ASCO annual meeting, Chicago, IL June 2–6, 2017.

[245] Paz-Ares, L., Chen, Y., Reinmuth, N., et al., Overall Survival with Durvalumab Plus Platinum-Etoposide in First-Line Extensive-Stage SCLC: Results from the CASPIAN Study [presentation], Presented at: World Conference on Lung Cancer, Barcelona, Spain, September 7–10, 2019.

applicant stated that IMFINZI®, in combination with standard chemotherapy, represents a new treatment option for patients with extensive stage small cell lung cancer, demonstrating statistically and clinically significant improved overall survival as compared to standard chemotherapy (Hazard ration [HR] 0.73; 95 percent CI 0.59–0.91; p=0.0047).[246]

The applicant asserts that, if approved, IMFINZI® in combination with chemotherapy would represent a new treatment option for ES–SCLC patients.

According to the applicant, SCLC differs significantly from NSCLC, in both its prevalence and prognosis. The applicant states that SCLC represents only 10–15 percent of all lung cancers, with approximately 30,000 new cases each year in the US. In contrast, the applicant states that NSCLC represents 84 percent of all lung cancers, with approximately 200,000 new cases each year.[247] The applicant states SCLC has an extremely poor prognosis, as noted previously, with an overall 5-year survival rate of 6 percent, and that ES–SCLC represents the overwhelming majority of SCLC cases at diagnosis, approximately 75 percent, with a 5-year survival rate closer to 3 percent.[248] [249] The applicant also describes treatment options as limited for ES–SCLC, as compared to patients with NSCLC. The applicant also states that many recent studies of the treatment of NSCLC have demonstrated positive outcomes with a variety of agents, including with combination treatments that the applicant describes as having different mechanisms of action.[250]

We note that we received an application for new technology add-on payments for FY 2021 for TECENTRIQ®, which received FDA approval on March 18, 2019 and is indicated, in combination with carboplatin and etoposide, for the first-line treatment of adult patients with ES–SCLC. Both IMFINZI® and TECENTRIQ® seem to be intended for similar patient populations and would involve the treatment of the same conditions; patients with locally advanced or metastatic urothelial carcinoma and patients with SCLC. We are interested in information on how these two technologies may differ from each other with respect to the substantial similarity criteria and newness criterion, to inform our analysis of whether IMFINZI® and TECENTRIQ® are substantially similar to each other and therefore should be considered as a single application for purposes of new technology add-on payments.

We are inviting public comments on whether IMFINZI® is substantially similar to an existing technology and whether it meets the newness criterion.

With respect to the cost criterion, the applicant conducted the following analysis to demonstrate that IMFINZI® meets the cost criterion. To identify cases that may be eligible for the use of IMFINZI®, the applicant searched the FY 2018 MedPAR LDS file for claims reporting an ICD–10–CM code of category C34 in combination with Z51.11 (Encounter for antineoplastic chemotherapy) or Z51.12 (Encounter for antineoplastic immunotherapy). The applicant also included any cases within MS–DRGs 180, 181, 182 with an ICD–10–CM diagnosis code from category C34 as the applicant believes hospitals may not always capture the encounter for chemotherapy. Based on the FY 2018 MedPAR LDS file, the applicant identified a total of 24,193 cases. Of the MS–DRGs with more than 11 cases, the applicant found 23,933 cases which were mapped to 12 unique MS–DRGs. The applicant excluded MS–DRGs with case volume less than 11 total cases.

Using these 23,933 cases, the applicant then calculated the unstandardized average charges per case for each MS–DRG. The applicant determined that it did not need to remove any charges as IMFINZI® is not expected to offset historical charges already included within the MS–DRGs. The applicant expects that ES–SCLC patients will receive their initial dose of IMFINZI® in the inpatient setting. The applicant then standardized the charges and inflated the charges by 1.11100 or 11.10 percent, the same inflation factor used by CMS to update the outlier threshold in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42629). The applicant then added the charges for IMFINZI® by converting the costs to a charge by dividing the cost by the national average cost-to-charge ratio of 0.189 for drugs from the FY 2020 IPPS/LTCH PPS final rule (84 FR 42179).

Based on the FY 2020 IPPS/LTCH PPS final rule correction notice data file thresholds, the average case-weighted threshold amount was $53,209. In the applicant's analysis, the final inflated average case-weighted standardized charge per case was $111,093. Because the final inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

As noted previously, we received an application for new technology add-on payments for FY 2021 for TECENTRIQ®. Both IMFINZI® and TECENTRIQ® seem to be intended for similar patients. The ICD–10–CM diagnosis codes and MS–DRGs in the cost analysis for IMFINZI® differ from those used in the cost analysis for TECENTRIQ®. Specifically, as noted previously, the applicant for IMFINZI® searched for category C34 in combination with Z51.11 or Z51.12, while the applicant for TECENTRIQ® only searched for claims with category C34. We are concerned as to why the diagnosis codes would differ between the cost analysis for IMFINZI® and for TECENTRIQ® as one analysis may lend more accuracy to the calculation depending which is more reflective of the applicable patient population. We are inviting public comment on whether IMFINZI® meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserts that IMFINZI® represents a substantial clinical improvement over existing technologies because it offers a treatment option for a patient population unresponsive to currently available treatments. The applicant also believes that it represents a substantial clinical improvement because the applicant states that the technology reduces mortality, decreases disease progression, and improves quality of life.

The CASPIAN clinical trial is a randomized, open-label, phase 3 trial at 209 sites across 23 countries. Eligible patients were adults with untreated ES–SCLC, with World Health Organization (WHO) performance status 0 or 1 and measurable disease as per Response Evaluation Criteria in Solid Tumors. Patients were randomly assigned (in a 1:1:1 ratio) to durvalumab plus platinum–etoposide; durvalumab plus tremelimumab plus platinum–etoposide; or platinum–etoposide alone. All drugs were administered intravenously. Platinum–etoposide consisted of etoposide 80–100 mg/m2 on days 1–3 of each cycle with investigator's choice of either

[246] Paz-Ares, L., Dvorkin, M., Chen, Y., et al., ''Durvalumab plus platinum-etoposide versus platinum-etoposide in first-line treatment of extensive-stage small-cell lung cancer (CASPIAN): a randomized, controlled, open-label, phase 3 trial [article and supplementary appendix],'' *Lancet,* 2019.

[247] Farago, A.F. et al., ''Current standards for clinical management of small cell lung cancer,'' *Translational Lung Cancer Research,* 2018, 7(1), pp. 69–79.

[248] Ibid.

[249] Thirumaran, R., Prendergast, G.C., Gilman, P.B., ''Cytotoxic chemotherapy in clinical treatment of cancer,'' In: Prendergast, G.C., Jaffee, E.M., editors, *Cancer immunotherapy: immune suppression and tumor growth,* USA: Elsevier Inc, 2007, p. 101–116, *http://dx.doi.org/10.1016/B978-012372551-6/50071-7.*

[250] Yang, S., Zhang, Z., Wang, Q., ''Emerging therapies for small cell lung cancer,'' *Journal of Hematology & Oncology,* 2019, 12(1), p. 47.

carboplatin area under the curve 5–6 mg/mL per min or cisplatin 75–80 mg/m2 (administered on day 1 of each cycle). Patients received up to four cycles of platinum–etoposide plus durvalumab 1500 mg with or without tremelimumab 75 mg every 3 weeks followed by maintenance durvalumab 1500 mg every 4 weeks in the immunotherapy groups and up to 6 cycles of platinum–etoposide every 3 weeks plus prophylactic cranial irradiation (investigator's discretion) in the platinum–etoposide group. The primary endpoint was overall survival in the intention-to-treat population. This study is registered at *ClinicalTrials.gov,* NCT03043872, and is ongoing. The applicant stated that the median OS was 13.0 months (95 percent CI, 11.5–14.8) for patients treated with IMFINZI® plus chemotherapy vs. 10.3 months (95 percent CI, 9.3–11.2) for SOC chemotherapy. It stated that the results also showed a sustained OS benefit with 34 percent survival at 18 months following treatment with IMFINZI® plus chemotherapy vs. 25 percent following SOC chemotherapy. No data was provided on patients treated with durvalumab plus tremelimumab plus platinum–etoposide as this was an interim analysis.[251]

The applicant further states that other key secondary endpoints demonstrated consistent and durable improvement for IMFINZI® plus chemotherapy, including a higher progression-free survival (PFS) rate at 12 months (17.5 percent vs. 4.7 percent), a 10 percent increase in confirmed objective response rate (ORR) (67.9 percent vs. 57.6 percent), and improved duration of response at 12 months (22.7 percent vs. 6.3 percent). The median Progression Free Survival was 5.1 months with IMFINZI® versus 5.4 months for the control arm, which was not significantly different.

The applicant states that in combination with etoposide and platinum-based chemotherapy, IMFINZI® provided a significant improvement in survival and notable changes in patient reported outcomes. According to the applicant, patients receiving IMFINZI® plus etoposide and platinum-based chemotherapy experienced reduced symptom burden over 12 months for pre-specified symptoms of fatigue, appetite loss, cough, dyspnea, and chest pain (based on adjusted mean change from baseline, MMRM). The applicant states a large difference over 12 months was observed for appetite loss in favor of IMFINZI® plus etoposide and platinum-based chemotherapy compared to standard-of-care etoposide and platinum-based chemotherapy. The applicant further states that patients receiving IMFINZI® plus etoposide and platinum-based chemotherapy also experienced longer time to deterioration in a broad range of patient-reported symptoms (for example, dyspnea, appetite loss, chest pain, arm/shoulder pain, other pain, insomnia, constipation, diarrhea), functioning (physical, cognitive, role, emotional, social), and Health Related Quality of Life (HRQoL) indicators, compared to cisplatin (EP).[252] [253] [254] [255]

As stated previously, the applicant asserted that IMFINZI® represents a substantial clinical improvement over existing technologies because it offers a treatment option for a patient population unresponsive to currently available treatments. The applicant explained that the CASPIAN study demonstrated the following endpoints: patient population baseline characteristics, treatment exposure, overall survival (including pre-specified subgroups), progression free survival, sites of progression, objective response rate, duration of response, and detailed safety analysis. All results provided comparison of the active IMFINZI® plus chemotherapy arm as compared to the standard of care chemotherapy alone arm.[256] We are concerned that the CASPIAN study is ongoing and the information is preliminary. Specifically, the three arms in the study have not yet been analyzed. Additionally, while the data shows a median survival benefit of about 3 months with treatment with IMFINZI®, we did not see any data that demonstrates significant improvement in median progression free survival. Also, while we recognize that the trials are ongoing and that the analysis of the three study arms is not complete, we are interested in additional information concerning adverse events to help us better understand the safety profile of IMFINZI®.

We are inviting public comment on whether IMFINZI® meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for IMFINZI® or at the New Technology Town Hall meeting.

i. KTE–X19

Kite Pharma submitted an application for new technology add-on payment for FY 2021 for KTE–X19. KTE–X19 is a CD19 directed genetically modified autologous T-cell immunotherapy for the treatment of adult patients with relapse and refractory (r/r) mantle cell lymphoma (MCL).

KTE–X19 is a form of chimeric antigen receptor (CAR) T-cell immunotherapy that modifies the patient's own T-cells to target and eliminate tumor cells. More specifically, according to the applicant, KTE–X19 is a single infusion product consisting of autologous T-cells that have been engineered to express an anti-CD19 chimeric antigen receptor. According to the applicant, this therapy targets the CD19 antigen on the cell surface of normal and malignant B-cells. The applicant stated that KTE–X19 is different from other previously approved technologies because it has a distinct cellular product that requires a unique manufacturing process. The applicant explained that KTE–X19's unique manufacturing process, as compared to YESCARTA®, results in differences in potency, cellular impurities, and formulation of the final products.

According to the applicant, MCL is a rare and aggressive subtype of non-Hodgkin lymphoma (NHL) with distinct

[251] Paz-Ares, L., Dvorkin, M., Chen, Y., et al., ''Durvalumab plus platinum-etoposide versus platinum-etoposide in first-line treatment of extensive-stage small-cell lung cancer (CASPIAN): A randomized, controlled, open-label, phase 3 trial,'' *Lancet,* 2019, *https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)32222-6/fulltext.* Accessed October 7, 2019.

[252] AstraZeneca Press Release, September 9, 2019, Available at: *https://www.astrazeneca-us.com/content/az-us/media/press-releases/2019/imfinzi-is-first-immunotherapy-to-show-both-significant-survival-benefit-and-improved-durable-responses-in-extensive-stage-small-cell-lung-cancer-09092019.html.*

[253] Paz-Ares, L., Chen, Y., Reinmuth, N., et al., Overall Survival with Durvalumab Plus Platinum-Etoposide in First-Line Extensive-Stage SCLC: Results from the CASPIAN Study [presentation], Presented at: World Conference on Lung Cancer, Barcelona, Spain, September 7–10, 2019.

[254] Paz-Ares, L., Dvorkin, M., Chen, Y., et al., ''Durvalumab plus platinum-etoposide versus platinum-etoposide in first-line treatment of extensive-stage small-cell lung cancer (CASPIAN): a randomized, controlled, open-label, phase 3 trial,'' *Lancet.* 2019, *https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)32222-6/fulltext.* Accessed October 7, 2019.

[255] Paz-Ares, L., Goldman, J.W., Garassino, M.C., et al., PD–L1 expression, patterns of progression and patient-reported outcomes (PROs) with durvalumab plus platinum-etoposide in ES–SCLC: Results from CASPIAN [presentation], Presented at European Society for Medical Oncology; Barcelona, Spain, September 27–October 1, 2019.

[256] Paz-Ares, L., Dvorkin, M., Chen, Y., et al., ''Durvalumab plus platinum-etoposide versus platinum-etoposide in first-line treatment of extensive-stage small-cell lung cancer (CASPIAN): A randomized, controlled, open-label, phase 3 trial [article and supplementary appendix],'' *Lancet,* 2019.

characteristics [257] [258] that accounts for 3–6% of all cases of NHL in the United States and differs from diffuse large B-cell lymphoma (another subtype of NHL).[259] [260] [261] The applicant cited that the overall incidence of MCL in the U.S. in 2018 was 3,500 with 5-year and 10-year prevalence of 12,000 and 18,000 cases.[262] Additionally, the applicant stated that the median age at diagnosis for patients with MCL is 68 years and the majority of patients are non-Hispanic white males.[263] MCL results from a malignant transformation of the B lymphocyle in the outer edge of a lymph node follicle (the mantle zone). Prognosis varies for r/r MCL, but the median survival for MCL is 3–5 years depending on the risk group (the Mantle Cell Lymphoma International Prognostic Index categorizes patients into low, intermediate and high risk groups), according to the applicant.[264] The first line therapy for newly diagnosed MCL routinely includes chemotherapy in combination with rituximab.[265] [266] [267] [268] [269] According to the applicant, rituximab is also the only approved therapy for maintenance for patients in remission. The median progression free survival ranges from 18–51 months with most of MCL patients eventually relapsing. The applicant contended that only 30–40% of patients end up with durable long-term remission after a chemoimmunotherapy first line therapy.[270] [271] [272]

The applicant indicated that there is no standard of care that exists for second-line and higher chemotherapy when a patient has relapsed or refractory MCL.[273] According to the applicant, second line therapies typically depend on the front line therapy utilized, comorbidities, the tumor's sensitivity to chemotherapy, and overall risk-benefit. Currently available options for second line therapy include: Cytotoxic chemotherapy, proteasome inhibitors, immunomodulatory drugs, tyrosine kinase inhibitors, and stem cell transplant (both autologous [ASCT] and allogenic stem cell transplant [allo-SCT]). According to the applicant, Bruton's tyrosine kinase (BTK) inhibitor, ibrutinib, is the most common third-line therapy used for patients with r/r MCL and has been shown to offer improvements over other chemotherapy-based regimens for r/r MCL patients. The applicant also referenced a more selective BTK inhibitor, acalabrutinib, which was approved in the US for the treatment of patients with r/r MCL.[274] [275]

With respect to the newness criterion, the applicant indicated that it submitted a biologics license application (BLA) for KTE–X19 on December 11, 2019 with a request for priority review. The applicant reported it anticipates receiving FDA approval by July 1, 2020. According to the applicant, KTE–X19 was granted breakthrough therapy designation for the treatment of patients with r/r MCL on June 15, 2018 and received an orphan drug designation in 2016 for the treatment of MCL, acute lymphoblastic leukemia and chronic lymphocytic leukemia. Under the current coding system, cases reporting the use of KTE–X19 would be coded with ICD–10–PCS codes XW033C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3) and XW043C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3), which are currently assigned to MS–DRG 016 (Autologous Bone Marrow Transplant with CC/MCC or T-Cell Immunotherapy). As discussed in section II.D.2.b. of the preamble of this proposed rule, we are proposing to assign cases reporting ICD–10–PCS procedure codes XW033C3 or XW043C3 to a proposed new MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy), which would also include cases reporting the use of KTE–X19, if approved and finalized. While we note that the applicant has submitted a request for a unique ICD–10–PCS code to describe the use of KTE–X19 beginning in FY 2021, the MS–DRG assignment of any applicable finalized codes describing the use of KTE–X19 will be addressed in the final rule.

As previously discussed, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion for substantial similarity, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, according to the applicant, KTE–X19 will be the first CAR T-cell immunotherapy indicated for the treatment of r/r MCL, if approved by FDA. The applicant further asserted that it does not use a substantially similar mechanism of action or involve the same treatment indication as any other existing therapy for the treatment of r/r MCL. The applicant asserts that it uses a different mechanism of action as other therapies because the unique manufacturing process results in differences in potency, cellular impurities, and formulation of the final

[257] Fakhri B, Kahl B. Current and emerging treatment options for mantle cell lymphoma. Ther Adv Hematol. 2017;8(8):223–34.

[258] National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology; B-cell Lymphomas, Version 1.2019 [November 30, 2018]. 2017 Available from: *https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf.*

[259] The Non-Hodgkin's Lymphoma Classification Project. A clinical evaluation of the International Lymphoma Study Group classification of non-Hodgkin's lymphoma. Blood. 1997;89(11):3909–3918.

[260] Zhou Y, et al. Incidence trends of mantle cell lymphoma in the United States between 1992 and 2004. Cancer. 2008;113(4):791–798.

[261] Teras LR, et al. 2016 US lymphoid malignancy statistics by World Health Organization subtypes CA Cancer J Clin. 2016;6:443–459.

[262] Kantar Health. CancerMPact® United States. September 2018, v1.2.

[263] Fu S, et al. Trends and variations in mantle cell lymphoma incidence from 1995 to 2013: A comparative study between Texas and National SEER areas. Oncotarget. 2017;8(68):112516–29.

[264] Cheah CY, et al. Mantle cell lymphoma. *J Clin Oncol.* 2016;34:1256–1269.

[265] *Ibid.*

[266] Kantar Health. CancerMPact® United States. September 2018, v1.2.

[267] Flinn IW, et al. First-line treatment of patients with indolent non-Hodgkin lymphoma or mantle-cell lymphoma with bendamustine plus rituximab versus R–CHOP or R–CVP: Results of the BRIGHT 5-year follow-up study. *J Clin Oncol.* 2019 Apr 20;37(12):984–991. doi: 10.1200/JCO.18.00605. Epub 2019 Feb 27.

[268] LaCasce AS, et al. Comparative outcome of initial therapy for younger patients with mantle cell lymphoma: An analysis from the NCCN NHL Database. *Blood.* 2012;19(9):2093–2099.

[269] Lenz G, et al. Immunochemotherapy with rituximab and cyclophosphamide, doxorubicin, vincristine, and prednisone significantly improves response and time to treatment failure, but not long-term outcome in patients with previously untreated mantle cell lymphoma: Results of a prospective randomized trial of the German Low Grade Lymphoma Study Group (GLSG). J Clin Oncol. 2005:23(9): 1984–1992.

[270] Flinn IW, et al. First-line treatment of patients with indolent non-Hodgkin lymphoma or mantle-cell lymphoma with bendamustine plus rituximab versus R–CHOP or R–CVP: Results of the BRIGHT 5-year follow-up study. *J Clin Oncol.* 2019 Apr 20;37(12):984–991. doi: 10.1200/JCO.18.00605. Epub 2019 Feb 27.

[271] LaCasce AS, et al. Comparative outcome of initial therapy for younger patients with mantle cell lymphoma: An analysis from the NCCN NHL Database. *Blood.* 2012;19(9):2093–2099.

[272] Lenz G, et al. Immunochemotherapy with rituximab and cyclophosphamide, doxorubicin, vincristine, and prednisone significantly improves response and time to treatment failure, but not long-term outcome in patients with previously untreated mantle cell lymphoma: Results of a prospective randomized trial of the German Low Grade Lymphoma Study Group (GLSG). J Clin Oncol. 2005:23(9): 1984–1992.

[273] Campo E, Rule S. Mantle cell lymphoma: evolving management strategies. *Blood.* 2015;125(1):48–55.

[274] Kantar Health. CancerMPact® United States. September 2018, v1.2.

[275] Vose JM. Mantle cell lymphoma: 2017 update on diagnosis, risk-stratification, and clinical management. Am J Hematol. 2017;92(8):806–813.

products. Furthermore, the applicant stated that functional autologous cellular therapy for the treatment of r/r MCL requires a customized product distinct from other currently available CAR T-cell therapy products, namely YESCARTA® and KYMRIAH®. The applicant stated it reviewed data from the FY 2018 100 percent MedPAR Hospital Limited Data Set to obtain a reference of currently available products used in the treatment of r/r MCL. The applicant stated that based on this analysis, available products used in the treatment of r/r MCL included: Chemotherapies, proteasome inhibitors, immunomodulatory agents, or BTK inhibitors. The applicant described KTE–X19 as an autologous CAR T-cell immunotherapy, which genetically modifies the patient's own T-cells to target and eliminate tumor cells for the treatment of r/r MCL and asserted that because KTE–X19 is an autologous CAR T-cell immunotherapy, it does not use the same mechanism of action as other treatments currently used to treat r/r MCL (chemotherapies, proteasome inhibitors, immunomodulatory agents, or BTK inhibitors).

To further note the differences between KTE–X19's mechanism of action and other available therapies for r/r MCL, the applicant stated that KTE–X19 represents a unique product that is customized for B-cell malignancies bearing high levels of circulating CD19-expressing tumor cells. Given these genetic modifications and differences, as previously described, the applicant described KTE–X19 as having a different mechanism of action from existing r/r MCL therapies.

The applicant described that the KTE–X19 construct encodes for the following domains of the CAR: An anti-human CD19 single-chain variable region fragment (scFv); the partial extracellular domain and complete transmembrane and intracellular signaling domains of human CD28, a lymphocyte co-stimulatory receptor that plays an important role in optimizing T-cell survival and function; and the cytoplasmic portion, including the signaling domain, of human CD3ζ, a component of the T-cell receptor complex.[276] The applicant referenced an April 2018 pre-BLA meeting with FDA, where the applicant contended that FDA determined that KTE–X19 qualified for a new BLA based on differences in the manufacturing process between KTE–X19 and YESCARTA®, which result in differences in potency, cellular impurities, and formation of the final products. The applicant further referenced that KTE–X19 has a different mechanism of action as compared to YESCARTA® given that the European Medicines Agency (EMA) deemed KTE–X19 and YESCARTA® as different products.

With respect to the second criterion for substantial similarity, whether a product is assigned to the same or a different MS–DRG, the applicant noted that CMS previously stated future CAR T-cell therapies would likely map to the same MS–DRG as other previously FDA-approved CAR T-cell therapies. However, the applicant asserted that KTE–X19 could not be reported using the same ICD–10–PCS codes as identified for YESCARTA® and KYMRIAH®. As previously noted, under the current coding system, cases reporting the use of KTE–X19 would be coded with ICD–10–PCS codes XW033C3 and XW043C3, which are currently assigned to MS–DRG 016, and which, for FY 2021, we are proposing to reassign to a new proposed MS–DRG 018 for CART-cell therapies. As also previously noted, the MS–DRG assignment of any applicable finalized codes describing the use of KTE–X19 will be addressed in the final rule. The applicant noted that the patients treated by YESCARTA® and KYMRIAH® are not assigned ICD–10–CM diagnosis code C83.10 (Mantle cell lymphoma, unspecified site), as would patients treated with KTE–X19. To further emphasize this point, the applicant stated that CMS indicated YESCARTA® and KYMRIAH® are intended to treat the same or similar disease: adult patients with r/r large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. The applicant further noted that the patients treated with YESCARTA® and KYMRIAH® are not identified by ICD–10–CM code C83.10 (Mantle cell lymphoma, unspecified site).

With respect to the third criterion for substantial similarity, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant described KTE–X19 as representing a therapy for a different type of disease, r/r MCL, as compared to YESCARTA® and KYMRIAH®. As previously mentioned, the applicant described that MCL results from a malignant transformation of a B lymphocyte in the outer edge of the lymph node follicle. The applicant further stated that diffuse large b-cell lymphoma (DLBCL), which YESCARTA® and KYMRIAH® treat, is defined as a neoplasm of large B cells arranged in a diffuse pattern. The applicant described this distinction as evidence that KTE–X19 treats a different subtype of NHL, r/r MCL, as compared to other FDA approved CAR T-cell therapies. However, we note that the applicant recognized in its application that MCL and DLBCL patients share similar clinical presentation of lymphadenopathy, splenomegaly and constitutional symptoms. The applicant also noted that the disease courses for MCL and DLBCL are different given that MCL has a unique molecular pathogenesis. The applicant also highlighted the high level of tumor cells in the peripheral blood, which is uncommon in DLBCL, to further illustrate that the two diseases are different, and asserted that this level of tumor cells requires a different and customizable treatment approach for the generation of autologous cellular therapies for MCL.

We have the following concerns regarding whether the technology meets the substantial similarity criteria and whether it should be considered new.

With respect to the first criterion for substantial similarity, based on the statements as previously summarized, the applicant asserted that KTE–X19 would provide a new treatment option for adult patients with r/r MCL and therefore is not substantially similar to any existing technologies. We note that for FY 2019 (83 FR 41299), CMS approved two CD19 directed CAR T-cell therapies, YESCARTA® and KYMRIAH®, for new technology add-on payments. While the applicant acknowledged that KTE–X19 is a form of CAR T-cell immunotherapy that modifies the patient's own T-cells, as are YESCARTA® and KYMRIAH®, the applicant asserted that the production process used by KTE–X19, as required by the disease indication, makes the therapy significantly different from YESCARTA® and KYMRIAH®. However, while the applicant stated how its technology is different from previously approved CAR T-cell therapies, KTE–X19 is also a CD19-directed T-cell immunotherapy for the purpose of treating patients with an aggressive subtype of NHL. Therefore, we express a potential concern that KTE–X19 has a similar mechanism of action to YESCARTA® and KYMRIAH®.

The applicant stated that KTE–X19 is a distinct cellular product and has a unique manufacturing process

[276] Nicholson IC, et al. Construction and characterisation of a functional CD19 specific single chain Fv fragment for immunotherapy of B lineage leukemia and lymphoma. *Molecular Immunology*. 1997;34(16–17):1157–65.

customized for B-cell malignancies with a high circulating tumor cell burden and designed to minimize the CD19-expressing tumor cells in the final product. We are concerned as to whether the differences the applicant described in the manufacturing process should be considered a different mechanism of action, as compared to previous CAR T-cell therapies.

With respect to the second criterion for substantial similarity, we note that as discussed in section II.D.2.b. of the preamble of this proposed rule, we are proposing to create new MS–DRG 018 for CAR T-cell therapies. As previously noted, under the current coding system, cases reporting the use of KTE–X19 would be coded with ICD–10–PCS codes XW033C3 and XW043C3, which are currently assigned to MS–DRG 016. Also as discussed in section II.D.2.b. of the preamble of this proposed rule, we are proposing to assign cases reporting ICD–10–PCS procedure codes XW033C3 or XW043C3 to a proposed new MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy). Should we finalize this proposal, we would also assign cases involving the use of KTE–X19 to this proposed new MS–DRG 018. We believe that cases reporting the use of KTE–X19 would be assigned to the same MS–DRG as existing CAR T-cell technologies.

With regard to the third criterion for substantial similarity, the applicant described that MCL results from a malignant transformation of a B lymphocyte in the outer edge of the lymph node follicle, while DLBCL, which YESCARTA® and KYMRIAH® treat, is defined by the applicant as a neoplasm of large B cells arranged in a diffuse pattern. As described by the applicant, MCL and DLBCL patients share similar clinical presentation of lymphadenopathy, splenomegaly and constitutional symptoms. We therefore express concern that this therapy may involve treatment of a similar type of disease when compared to existing CAR T-cell therapies.

We are inviting public comments on whether KTE–X19 is substantially similar to other technologies and whether KTE–X19 meets the newness criterion.

With regard to the cost criterion, the applicant searched the FY 2018 MedPAR claims data file to identify potential cases representing patients who may be eligible for treatment using KTE–X19. The applicant identified claims that reported an ICD–10–CM diagnosis code of ICD–10–CM C83.10 (Mantle cell lymphoma, unspecified site). The applicant stated that claims reporting ICD–10–CM code C83.10 would not involve the use of the other two approved CAR T-cell therapies because those therapies are not used to treat this diagnosis, MCL. As such, the applicant stated that it used C83.10 to identify potential MCL cases and ICD–10–PCS codes XW033C3 and XW043C3 to identify patients receiving CAR T-cell therapy. In its analysis, the applicant identified two sets of cohorts (Primary Cohort and Sensitivity Analysis Cohort) to assess whether this therapy met the cost criterion. The ICD–10–PCS procedure codes listed in the table in this section of this rule were used to identify claims involving chemotherapy and the applicant noted that these were used for both cohorts.

The new technology add-on payment Primary Cohort included cases with an ICD–10–CM principal diagnosis of MCL, at least one procedure code indicating receipt of chemotherapy, and no ICD–10–PCS procedure codes indicating CAR T-cell therapy. The applicant believed the Primary Cohort most closely aligned with the characteristics and health of r/r MCL patients who would receive KTE–X19 given that this cohort includes patients with far advanced disease (comparable to the ZUMA–2 study, as discussed later in this section). The Sensitivity Analysis Cohort included patients with the ICD–10–CM principal or secondary diagnosis of MCL, at least one procedure code indicating receipt of chemotherapy, and no ICD–10–PCS procedure codes indicating CAR T-cell therapy. The claim search conducted by the applicant resulted in 293 claims in the Primary Cohort, mapped to 13 MS–DRGs, and 953 claims in the Sensitivity Analysis Cohort, mapped to 72 MS–DRGs using the FY 2018 MedPAR Hospital LDS based on the requirements for each cohort outlined by the applicant.

BILLING CODE 4120–01–P

ICD-10-PCS Procedure Codes Describing Chemotherapy

ICD-10-PCS Code	Description
3E00X05	Introduction of other antineoplastic into skin and mucous membranes, external approach
3E00X0M	Introduction of monoclonal antibody into skin and mucous membranes, external approach
3E01305	Introduction of other antineoplastic into subcutaneous tissue, percutaneous approach
3E0130M	Introduction of monoclonal antibody into subcutaneous tissue, percutaneous approach
3E02305	Introduction of other antineoplastic into muscle, percutaneous approach
3E0230M	Introduction of monoclonal antibody into muscle, percutaneous approach
3E03002	Introduction of high-dose interleukin-2 into peripheral vein, open approach
3E03003	Introduction of low-dose interleukin-2 into peripheral vein, open approach
3E03005	Introduction of other antineoplastic into peripheral vein, open approach
3E0300M	Introduction of monoclonal antibody into peripheral vein, open approach
3E0300P	Introduction of clofarabine into peripheral vein, open approach
3E030GN	Introduction of blood brain barrier disruption substance into peripheral vein, open approach
3E03302	Introduction of high-dose interleukin-2 into peripheral vein, percutaneous approach
3E03303	Introduction of low-dose interleukin-2 into peripheral vein, percutaneous approach
3E03305	Introduction of other antineoplastic into peripheral vein, percutaneous approach
3E0330M	Introduction of monoclonal antibody into peripheral vein, percutaneous approach
3E0330P	Introduction of clofarabine into peripheral vein, percutaneous approach
3E033GN	Introduction of blood brain barrier disruption substance into peripheral vein, percutaneous approach
3E04002	Introduction of high-dose interleukin-2 into central vein, open approach
3E04003	Introduction of low-dose interleukin-2 into central vein, open approach
3E04005	Introduction of other antineoplastic into central vein, open approach
3E0400M	Introduction of monoclonal antibody into central vein, open approach
3E0400P	Introduction of clofarabine into central vein, open approach
3E040GN	Introduction of blood brain barrier disruption substance into central vein, open approach
3E04302	Introduction of high-dose interleukin-2 into central vein, percutaneous approach
3E04303	Introduction of low-dose interleukin-2 into central vein, percutaneous approach
3E04305	Introduction of other antineoplastic into central vein, percutaneous approach
3E0430M	Introduction of monoclonal antibody into central vein, percutaneous approach
3E0430P	Introduction of clofarabine into central vein, percutaneous approach
3E043GN	Introduction of blood brain barrier disruption substance into central vein, percutaneous approach
3E05002	Introduction of high-dose interleukin-2 into peripheral artery, open approach
3E05003	Introduction of low-dose interleukin-2 into peripheral artery, open approach
3E05005	Introduction of other antineoplastic into peripheral artery, open approach
3E0500M	Introduction of monoclonal antibody into peripheral artery, open approach
3E0500P	Introduction of clofarabine into peripheral artery, open approach
3E050GN	Introduction of blood brain barrier disruption substance into peripheral artery, open approach
3E05302	Introduction of high-dose interleukin-2 into peripheral artery, percutaneous approach
3E05303	Introduction of low-dose interleukin-2 into peripheral artery, percutaneous approach
3E05305	Introduction of other antineoplastic into peripheral artery, percutaneous approach

ICD-10-PCS Code	Description
3E0530M	Introduction of monoclonal antibody into peripheral artery, percutaneous approach
3E0530P	Introduction of clofarabine into peripheral artery, percutaneous approach
3E053GN	Introduction of blood brain barrier disruption substance into peripheral artery, percutaneous approach
3E06002	Introduction of high-dose interleukin-2 into central artery, open approach
3E06003	Introduction of low-dose interleukin-2 into central artery, open approach
3E06005	Introduction of other antineoplastic into central artery, open approach
3E0600M	Introduction of monoclonal antibody into central artery, open approach
3E0600P	Introduction of clofarabine into central artery, open approach
3E060GN	Introduction of blood brain barrier disruption substance into central artery, open approach
3E06302	Introduction of high-dose interleukin-2 into central artery, percutaneous approach
3E06303	Introduction of low-dose interleukin-2 into central artery, percutaneous approach
3E06305	Introduction of other antineoplastic into central artery, percutaneous approach
3E0630M	Introduction of monoclonal antibody into central artery, percutaneous approach
3E0630P	Introduction of clofarabine into central artery, percutaneous approach
3E063GN	Introduction of blood brain barrier disruption substance into central artery, percutaneous approach
3E09305	Introduction of other antineoplastic into nose, percutaneous approach
3E0930M	Introduction of monoclonal antibody into nose, percutaneous approach
3E09705	Introduction of other antineoplastic into nose, via natural or artificial opening
3E0970M	Introduction of monoclonal antibody into nose, via natural or artificial opening
3E09X05	Introduction of other antineoplastic into nose, external approach
3E09X0M	Introduction of monoclonal antibody into nose, external approach
3E0A305	Introduction of other antineoplastic into bone marrow, percutaneous approach
3E0A30M	Introduction of monoclonal antibody into bone marrow, percutaneous approach
3E0B305	Introduction of other antineoplastic into ear, percutaneous approach
3E0B30M	Introduction of monoclonal antibody into ear, percutaneous approach
3E0B705	Introduction of other antineoplastic into ear, via natural or artificial opening
3E0B70M	Introduction of monoclonal antibody into ear, via natural or artificial opening
3E0BX05	Introduction of other antineoplastic into ear, external approach
3E0BX0M	Introduction of monoclonal antibody into ear, external approach
3E0C305	Introduction of other antineoplastic into eye, percutaneous approach
3E0C30M	Introduction of monoclonal antibody into eye, percutaneous approach
3E0C705	Introduction of other antineoplastic into eye, via natural or artificial opening
3E0C70M	Introduction of monoclonal antibody into eye, via natural or artificial opening
3E0CX05	Introduction of other antineoplastic into eye, external approach
3E0CX0M	Introduction of monoclonal antibody into eye, external approach
3E0D305	Introduction of other antineoplastic into mouth and pharynx, percutaneous approach
3E0D30M	Introduction of monoclonal antibody into mouth and pharynx, percutaneous approach
3E0D705	Introduction of other antineoplastic into mouth and pharynx, via natural or artificial opening
3E0D70M	Introduction of monoclonal antibody into mouth and pharynx, via natural or artificial opening
3E0DX05	Introduction of other antineoplastic into mouth and pharynx, external approach
3E0DX0M	Introduction of monoclonal antibody into mouth and pharynx, external approach
3E0E305	Introduction of other antineoplastic into products of conception, percutaneous approach

ICD-10-PCS Code	Description
3E0E30M	Introduction of monoclonal antibody into products of conception, percutaneous approach
3E0E705	Introduction of other antineoplastic into products of conception, via natural or artificial opening
3E0E70M	Introduction of monoclonal antibody into products of conception, via natural or artificial opening
3E0E805	Introduction of other antineoplastic into products of conception, via natural or artificial opening endoscopic
3E0E80M	Introduction of monoclonal antibody into products of conception, via natural or artificial opening endoscopic
3E0F305	Introduction of other antineoplastic into respiratory tract, percutaneous approach
3E0F30M	Introduction of monoclonal antibody into respiratory tract, percutaneous approach
3E0F705	Introduction of other antineoplastic into respiratory tract, via natural or artificial opening
3E0F70M	Introduction of monoclonal antibody into respiratory tract, via natural or artificial opening
3E0F805	Introduction of other antineoplastic into respiratory tract, via natural or artificial opening endoscopic
3E0F80M	Introduction of monoclonal antibody into respiratory tract, via natural or artificial opening endoscopic
3E0G305	Introduction of other antineoplastic into upper GI, percutaneous approach
3E0G30M	Introduction of monoclonal antibody into upper GI, percutaneous approach
3E0G705	Introduction of other antineoplastic into upper GI via natural or artificial opening
3E0G70M	Introduction of monoclonal antibody into upper GI via natural or artificial opening
3E0G805	Introduction of other antineoplastic into upper GI via natural or artificial opening endoscopic
3E0G80M	Introduction of monoclonal antibody into upper GI, via natural or artificial opening endoscopic
3E0H305	Introduction of other antineoplastic into lower GI, percutaneous approach
3E0H30M	Introduction of monoclonal antibody into lower GI, percutaneous approach
3E0H705	Introduction of other antineoplastic into lower GI, via natural or artificial opening
3E0H70M	Introduction of monoclonal antibody into lower GI, via natural or artificial opening
3E0H805	Introduction of other antineoplastic into lower GI, via natural or artificial opening endoscopic
3E0H80M	Introduction of monoclonal antibody into lower GI, via natural or artificial opening endoscopic
3E0J305	Introduction of other antineoplastic into biliary and pancreatic tract, percutaneous approach
3E0J30M	Introduction of monoclonal antibody into biliary and pancreatic tract, percutaneous approach
3E0J705	Introduction of other antineoplastic into biliary and pancreatic tract, via natural or artificial opening
3E0J70M	Introduction of monoclonal antibody into biliary and pancreatic tract, via natural or artificial opening
3E0J805	Introduction of other antineoplastic into biliary and pancreatic tract, via natural or artificial opening endoscopic
3E0J80M	Introduction of monoclonal antibody into biliary and pancreatic tract, via natural or artificial opening endoscopic
3E0K305	Introduction of other antineoplastic into genitourinary tract, percutaneous approach
3E0K30M	Introduction of monoclonal antibody into genitourinary tract, percutaneous approach
3E0K705	Introduction of other antineoplastic into genitourinary tract, via natural or artificial opening
3E0K70M	Introduction of monoclonal antibody into genitourinary tract, via natural or artificial opening
3E0K805	Introduction of other antineoplastic into genitourinary tract, via natural or artificial opening endoscopic
3E0K80M	Introduction of monoclonal antibody into genitourinary tract, via natural or artificial opening endoscopic
3E0L305	Introduction of other antineoplastic into pleural cavity, percutaneous approach
3E0L30M	Introduction of monoclonal antibody into pleural cavity, percutaneous approach
3E0L705	Introduction of other antineoplastic into pleural cavity, via natural or artificial opening
3E0L70M	Introduction of monoclonal antibody into pleural cavity, via natural or artificial opening
3E0M305	Introduction of other antineoplastic into peritoneal cavity, percutaneous approach
3E0M30M	Introduction of monoclonal antibody into peritoneal cavity, percutaneous approach
3E0M705	Introduction of other antineoplastic into peritoneal cavity, via natural or artificial opening

ICD-10-PCS Code	Description
3E0M70M	Introduction of monoclonal antibody into peritoneal cavity, via natural or artificial opening
3E0N305	Introduction of other antineoplastic into male reproductive, percutaneous approach
3E0N30M	Introduction of monoclonal antibody into male reproductive, percutaneous approach
3E0N705	Introduction of other antineoplastic into male reproductive, via natural or artificial opening
3E0N70M	Introduction of monoclonal antibody into male reproductive, via natural or artificial opening
3E0N805	Introduction of other antineoplastic into male reproductive, via natural or artificial opening endoscopic
3E0N80M	Introduction of monoclonal antibody into male reproductive, via natural or artificial opening endoscopic
3E0P305	Introduction of other antineoplastic into female reproductive, percutaneous approach
3E0P30M	Introduction of monoclonal antibody into female reproductive, percutaneous approach
3E0P705	Introduction of other antineoplastic into female reproductive, via natural or artificial opening
3E0P70M	Introduction of monoclonal antibody into female reproductive, via natural or artificial opening
3E0P805	Introduction of other antineoplastic into female reproductive, via natural or artificial opening endoscopic
3E0P80M	Introduction of monoclonal antibody into female reproductive, via natural or artificial opening endoscopic
3E0Q005	Introduction of other antineoplastic into cranial cavity and brain, open approach
3E0Q00M	Introduction of monoclonal antibody into cranial cavity and brain, open approach
3E0Q305	Introduction of other antineoplastic into cranial cavity and brain, percutaneous approach
3E0Q30M	Introduction of monoclonal antibody into cranial cavity and brain, percutaneous approach
3E0Q705	Introduction of other antineoplastic into cranial cavity and brain, via natural or artificial opening
3E0Q70M	Introduction of monoclonal antibody into cranial cavity and brain, via natural or artificial opening
3E0R302	Introduction of high-dose interleukin-2 into spinal canal, percutaneous approach
3E0R303	Introduction of low-dose interleukin-2 into spinal canal, percutaneous approach
3E0R305	Introduction of other antineoplastic into spinal canal, percutaneous approach
3E0R30M	Introduction of monoclonal antibody into spinal canal, percutaneous approach
3E0S302	Introduction of high-dose interleukin-2 into epidural space, percutaneous approach
3E0S303	Introduction of low-dose interleukin-2 into epidural space, percutaneous approach
3E0S305	Introduction of other antineoplastic into epidural space, percutaneous approach
3E0S30M	Introduction of monoclonal antibody into epidural space, percutaneous approach
3E0U305	Introduction of other antineoplastic into joints, percutaneous approach
3E0U30M	Introduction of monoclonal antibody into joints, percutaneous approach
3E0V305	Introduction of other antineoplastic into bones, percutaneous approach
3E0V30M	Introduction of monoclonal antibody into bones, percutaneous approach
3E0W305	Introduction of other antineoplastic into lymphatics, percutaneous approach
3E0W30M	Introduction of monoclonal antibody into lymphatics, percutaneous approach
3E0Y305	Introduction of other antineoplastic into pericardial cavity, percutaneous approach
3E0Y30M	Introduction of monoclonal antibody into pericardial cavity, percutaneous approach
3E0Y705	Introduction of other antineoplastic into pericardial cavity, via natural or artificial opening
3E0Y70M	Introduction of monoclonal antibody into pericardial cavity, via natural or artificial opening
XW03351	Introduction of blinatumomab antineoplastic immunotherapy into peripheral vein, percutaneous approach, new technology group 1
XW04351	Introduction of blinatumomab antineoplastic immunotherapy into central vein, percutaneous approach, new technology group 1

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The applicant inflated the charges from the FY 2018 MedPAR claims data by applying the 2-year inflation factor used in the FY 2020 IPPS final rule to calculate outlier threshold charges (1.11100). The applicant stated they then standardized the charges. The applicant stated that the cases representing patients who had received chemotherapy, as reflected by the Medicare claims data, would generally not receive both chemotherapy and KTE–X19 as an inpatient because conditioning chemotherapy would be administered in the outpatient setting before the patient would be admitted for KTE–X19 infusion and monitoring. Otherwise, the applicant asserted that patients receiving KTE–X19 would be expected to incur similar charges to those cases in the Medicare claims data for patients with a primary diagnosis of MCL and receiving chemotherapy (Primary Cohort). In its analysis, the applicant noted that in the FY 2018 MedPAR Hospital LDS, charges for chemotherapy drugs were grouped with charges for oncology, diagnostic radiology, therapeutic radiology, nuclear medicine, CT scans, and other imaging services. The applicant believed that removing all radiology charges would understate the cost of adverse event (AE) clinical management for KTE–X19 patients needed. The applicant found that when using data from the Q4 2017 and Q1 Q3 2018 Standard Analytic files and comparing total chemotherapy charges to total radiology charges, 2 percent of radiology charges were chemotherapy charges, on average. Therefore, instead of removing all radiology charges, the applicant excluded 2 percent of the radiology charge amount to capture the effect of removing chemotherapy pharmacy charges.

The applicant stated that when comparing the Primary Cohort to the MS–DRG 016 average case-weighed threshold amount (based on the FY 2020 IPPS/LTCH PPS final rule correction notice data file thresholds for FY 2021), the final inflated average case-weighted standardized charge per case of $201,459 exceeded the average case-weighted threshold amount of $170,573 by $30,886 without consideration of KTE–X19 charges. The applicant stated that because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the therapy meets the cost criterion.

When conducting the same review to assess cost for the Sensitivity Analysis Cohort, the applicant noted that the Sensitivity Analysis Cohort did not meet the cost criterion when compared to the MS–DRG 016 average case-weighted threshold amount (based on the FY 2020 IPPS/LTCH PPS final rule correction notice data file thresholds for FY 2021). As reported by the applicant, the final inflated average case-weighted standardized charge per case of $111,531 did not exceed the average case-weighted threshold amount of $170,573 (difference of $59,042) without consideration of KTE–X19 charges. However, the applicant noted that considering the cost of currently marketed CAR T-cell therapies, this Sensitivity Analysis Cohort would have met the cost criterion if it considered KTE–X19 charges. The applicant further noted that the characteristics of this cohort's patient population do not represent the characteristics of the population that would receive KTE–X19.

Because the final inflated average case-weighted standardized charge per case for the Primary Cohort exceeds the average case-weighted threshold amount for MS–DRG 016, the applicant maintained that the technology meets the cost criterion.

We note that the applicant, along with other CAR T-cell therapy manufacturers, have requested CMS use existing data to create a new MS–DRG specifically for CAR T-cell therapies. Currently, as previously noted, procedures involving CAR T-cell therapies are identified with ICD–10–PCS procedure codes XW033C3 and XW043C3. In the FY 2019 IPPS/LTCH PPS final rule, we finalized our proposal to assign cases reporting these ICD–10–PCS procedure codes to MS–DRG 016 and to revise the title of this MS–DRG to ''Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy'' effective beginning FY 2019. As discussed in section II.D.2.b. of the preamble of this proposed rule, for FY 2021, we are proposing to create a new MS–DRG 018, ''Chimeric Antigen Receptor (CAR) T-cell Immunotherapy.'' If finalized, this new MS–DRG for CAR T-cell therapy cases would include any approved procedure codes to describe cases involving the use of KTE–X19. We are also proposing to modify the structure of MS–DRG 016 by removing procedure codes XW033C3 and XW043C3 and to revise the title to ''Autologous Bone Marrow Transplant with CC/MCC'' to reflect the proposed restructuring. We refer readers to section II.E.2.b of the preamble of this proposed rule for a discussion of our proposals regarding the development of the relative weights for this proposed new MS–DRG for CAR T-cell therapy and to section IV.I. of the preamble of this proposed rule for a discussion of our proposal for a payment adjustment for clinical trial cases assigned to this proposed new MS–DRG. In this section of this rule we discuss the impact of our proposal to create new MS–DRG 018 for CAR T-cell therapies with regard to the new technology add-on payment.

As we have discussed in prior rulemaking with regard to the potential creation of a new MS–DRG for CAR T-cell therapies (83 FR 41172), if a new MS–DRG were to be created, then consistent with section 1886(d)(5)(K)(ix) of the Act, there may no longer be a need for a new technology add-on payment under section 1886(d)(5)(K)(ii)(III) of the Act. Section 1886(d)(5)(K)(ix) of the Act requires that, before establishing any add-on payment for a new medical service or technology, the Secretary shall seek to identify one or more DRGs associated with the new technology, based on similar clinical or anatomical characteristics and the costs of the technology and assign the new technology into a DRG where the average costs of care most closely approximate the costs of care using the new technology. As discussed in previous rulemaking (71 FR 47996), no add-on payment will be made if the new technology is assigned to a DRG that most closely approximates its costs.

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49481 and 49482) in the discussion of whether the WATCHMAN® System met the cost criterion for a new technology add-on payment, we discussed whether the threshold value associated with a proposed new MS–DRG should be considered in determining whether the applicant meets the cost criterion. We also discussed instances in the past where the coding associated with a new technology application is included in a finalized policy to change one or more MS–DRGs. For example, in the FY 2013 IPPS/LTCH PPS final rule, we described the cost analysis for the Zenith® Fenestrated Abdominal Aortic Aneurysm Endovascular Graft, which was identified by ICD–9–CM procedure code 39.78 (Endovascular implantation of branching or fenestrated graft(s) in aorta). In that same rule, we finalized a change to the assignment of that procedure code, reassigning it from MS–DRGs 252, 253, and 254 to MS–DRGs 237 and 238. Because of that change, we determined that, for FY 2013, in order for the Zenith® Fenestrated Abdominal Aortic Aneurysm Endovascular Graft to meet the cost criteria, it must demonstrate that the average case-weighted standardized charge per case exceeds the thresholds for MS–DRGs 237 and 238 (77 FR 53360). We noted that, in that example, MS–DRGs 237 and

238 existed previously; therefore, thresholds that were 75 percent of one standard deviation beyond the geometric mean standardized charge for these MS–DRGs were available to the public in Table 10 at the time the application was submitted. (We note that for fiscal years prior to FY 2020, Table 10 included the cost thresholds used to evaluate applications for new technology add-on payments for the next fiscal year.) In the FY 2016 IPPS/LTCH PPS proposed rule, we stated that in the case of WATCHMAN® System, if MS–DRGs 273 and 274 were to be finalized for FY 2016, we recognized that thresholds that are 75 percent of one standard deviation beyond the geometric mean standardized charge would not have been available at the time the application was submitted. We stated that we believed that it could be appropriate for the applicant to demonstrate that the average case weighted standardized charge per case exceeded these thresholds for MS–DRGs 273 and 274. Accordingly, we made available supplemental threshold values on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html* that were calculated using the data used to generate the FY 2015 IPPS/LTCH PPS Table 10 and reassigned the procedure codes in accordance with the finalized policies discussed in section II.G.3.b. of the preamble of the FY 2016 IPPS/LTCH PPS final rule. In the FY 2016 IPPS/LTCH PPS proposed rule, we invited public comments on whether considering these supplemental threshold values as part of the cost criterion evaluation for this application was appropriate and also on how to address similar future situations in a broader policy context should they occur.

After consideration of the comments, in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49482) we stated that we agreed with the commenters that we should evaluate the cost threshold in effect at the time the new technology add-on payment application is submitted to determine if an applicant exceeds the cost threshold. We stated that we agreed with commenters that this policy is most predictable for applicants. We also stated that we were maintaining our current policy to use the thresholds issued with each final rule for the upcoming fiscal year when making a determination to continue add-on payments for those new technologies that were approved for new technology add-on payments from the prior fiscal year.

At the time of the FY 2016 final rule, in applying this policy, we did not anticipate the onset of new, extremely high cost, technologies such as CAR T-cell therapy, nor such significant variance between the thresholds at the time of application and the thresholds based on the finalized MS–DRG assignment for the upcoming year. For example, in the FY 2016 final rule, the difference between the MS–DRG threshold amount for MS–DRGs 237 ($121,777) and 238 ($87,602) set forth in Table 10 associated with the FY 2015 final rule, and the supplemental MS–DRG threshold amount based on the proposed new MS–DRGs 273 ($95,542) and 274 ($77,230), was $26,235 and $10,372 respectively. By comparison, based on the data file released with the FY 2021 final rule (and corresponding correction notice) for FY 2022 applications, the threshold amount for MS–DRG 16 is $170,573. However, the threshold amount for proposed new MS–DRG 018 (in the data file released with this proposed rule) is $1,237,393, which is more than 7 times greater.

In light of the development of new technologies, such as CAR T-cell therapies, and the more substantial shifts in the MS–DRG threshold amounts that may result from the reassignment of new technologies for the upcoming fiscal year, we believe it is appropriate to revisit the policy described in the FY 2016 final rule. While we continue to believe that predictability is important, we also believe payment accuracy is equally important. Thus, we believe that it is necessary to balance predictability with a more accurate evaluation of whether a new technology meets the new technology add-on payment cost criterion by using threshold values that are consistent with how the cases involving the use of the new technology will be paid for in the upcoming fiscal year. Therefore, we are proposing to revise our policy in situations when the procedure coding associated with a new technology application is proposed to be assigned to a proposed new MS–DRG. Specifically, we are proposing that effective for FY 2022, for applications for new technology add-on payments and previously approved technologies that may continue to receive new technology add-on payments, the proposed threshold for a proposed new MS–DRG for the upcoming fiscal year would be used to evaluate the cost criterion for technologies that would be assigned to a proposed new MS–DRG.

For example, consider a technology that would be coded using procedure codes assigned to MS–DRG ABC at the time of its application for FY 2022, and then the procedure coding associated with the new technology is proposed to be assigned to a proposed new MS–DRG XYZ in the FY 2022 proposed rule. Instead of using the threshold for MS–DRG ABC based on the data file released with the FY 2021 final rule for FY 2022 applications, we are proposing to use the proposed threshold for the newly proposed MS–DRG XYZ based on the data file released with the FY 2022 proposed rule, which would otherwise contain the proposed thresholds for FY 2023 applications. We believe using the proposed rule thresholds for the proposed new MS–DRG would further promote payment accuracy by using the latest data available to assess how the technology would be paid for in the upcoming fiscal year, if the proposed reassignment to the new MS–DRG was finalized, while also providing the applicant and the public adequate time to analyze whether the technology meets the cost criterion using these proposed thresholds and to provide public comment following the proposed rule.

We believe it is important that the cost criterion be applied in a manner that accurately reflects the anticipated payment for the technology. In assessing the adequacy of the otherwise applicable MS–DRG payment rate for a high cost new technology, where the reassignment of such a technology to a proposed new MS–DRG may result in a substantial change in the MS–DRG threshold amounts, we believe that it is necessary to evaluate that technology using the proposed thresholds for the newly proposed MS–DRG to which the technology would be reassigned.

We believe that this policy is also consistent with section 1886(d)(5)(K)(ix) of the Act which, as previously noted, requires that before establishing any add-on payment for a new medical service or technology, the Secretary seek to identify one or more DRGs associated with the new technology, based on similar clinical or anatomical characteristics and the costs of the technology, and assign the new technology into a DRG where the average costs of care most closely approximate the costs of care using the new technology. This provision further states that no add-on payment will be made with respect to such new technology. As we have noted in prior rulemaking with regard to the CAR T-cell therapies (83 FR 41172), if a new MS–DRG were to be created, then consistent with section 1886(d)(5)(K)(ix) of the Act, there may no longer be a need for a new technology add-on payment under section 1886(d)(5)(K)(ii)(III) of the Act.

For these reasons, for purposes of FY 2021 new technology add-on payments,

we are proposing to evaluate the cost criterion for the CAR T-cell therapy technologies using the proposed threshold for the newly proposed MS–DRG to which the procedure codes describing the use of the CAR T-cell therapies would be assigned in FY 2021 (MS–DRG 018). This proposed policy would apply to the new FY 2021 CAR T-cell therapy applications, KTE–X19 and Liso-cel, and those CAR T-cell therapies previously approved for new technology add-on payments, KYMRIAH® and YESCARTA®.

As such, we are proposing to evaluate whether KTE–X19 meets the cost criterion using the proposed new MS–DRG 018 threshold amount of $1,237,393. As previously mentioned and reported by the applicant, the final inflated average case-weighted standardized charge per case for KTE–X19 was $201,459 for the Primary Cohort. As previously noted, this figure does not include the cost of the technology. However, we now have cases involving the use of CAR T-cell therapy within the FY 2019 MedPAR data that we believe may reflect cases that could be eligible for KTE–X19 or which can be used to approximate the charges for KTE–X19 to estimate the average standardized charge per case for purposes of this proposed rule. This charge information from the FY 2019 MedPAR data can be found in the FY 2021 Proposed Before Outliers Removed (BOR) File (available on the CMS website) for Version 38 of the MS–DRGs. Based on information from the FY 2021 Proposed BOR File for Version 38 of the MS–DRGs, the standardized charge per case for MS–DRG 018 is $913,224. The average case-weighted threshold amount based on the proposed new MS–DRG 018 is $1,237,393. Because this estimated average case-weighted standardized charge per case does not exceed the average case-weighted threshold amount for proposed MS–DRG 018, we do not believe the technology would meet the cost criterion. We note that this analysis is based on CMS data. The applicant conducted its own analysis as previously described that did not include the cost of the technology. We welcome additional information from the applicant regarding the cost of KTE–X19 to inform our determination for the final rule regarding whether the applicant meets the cost criterion based on the applicant's cost analysis.

We invite public comment on our proposal, for purposes of FY 2021 new technology add-on payments for CAR T-cell therapy technologies, to evaluate the cost criterion using the proposed threshold for the newly proposed MS–DRG 018 to which the procedure codes describing the use of the CAR T-cell therapies would be assigned in FY 2021, and on whether KTE–X19 meets the cost criterion based on this proposal. We also invite public comment on our proposal to use the proposed threshold for the upcoming fiscal year for any proposed new MS–DRG to evaluate the cost criterion for technologies that would be assigned to the proposed new MS–DRG, beginning with FY 2022 new technology add-on payments for all other non-CAR T-cell therapy technologies.

With respect to the substantial clinical improvement criterion, the applicant asserted that KTE–X19 represents a new treatment option for an adult patient population unresponsive to, or ineligible for, currently available treatments. The applicant also believes that the use of KTE–X19 significantly improves clinical outcomes for a patient with r/r MCL as compared to currently available therapies, including BTK inhibitors. The applicant stated that KTE–X19 provides access to a treatment option for patients with r/r MCL who have not been responsive to first line or second line therapies. The applicant provided further detail regarding these assertions, referencing the results of a Phase 2 study and historical and meta analyses, which are summarized in this section of this rule.

The applicant asserted that the use of KTE–X19 significantly improves clinical outcomes for a patient population as compared to currently available treatments. The applicant contended that Bruton's tyrosine kinase (BTK) inhibitor, ibrutinib, is the most common third-line therapy used for patients with r/r MCL and has been shown to offer improvements over other chemotherapy-based regimens for r/r MCL patients. The applicant also referenced a more selective BTK inhibitor, acalabrutinib, which was approved in the US for the treatment of patients with r/r MCL.[277] [278] In registrational trials, the objective response rates and complete response rates were 66% and 17%, respectively for ibrutinib, and 81% and 40%, respectively, for acalabrutinib.[279] [280] The applicant contended that primary and secondary resistance to BTK inhibitors [281] is common, and subsequent therapies currently available are minimally effective.[282] [283] [284] The applicant further summarized two retrospective studies that showed patients with r/r MCL with ≥3 prior lines of therapy before receiving the BTK inhibitor had an objective response rate of approximately 25% to BTK salvage therapy.[285] [286] The applicant submitted supplemental information describing two additional studies looking at the outcomes for patients receiving BTK inhibitors who had received previous therapies for their r/r MCL. A study by Regny and colleagues [287] studied 67 subjects who received BTK inhibitor treatment who then received a regimen of rituximab, bendamustine, bortezomib, and dexamethasone (RiVBD). The objective response rate for the 12 patients that had previously received ibrutinib was 67% and the median duration of response was 17 months.[288] The second study, by McCulloch and colleagues, was a retrospective study of 35 subjects with r/r MCL who had prior BTK inhibitor treatment and subsequently went on to receive a regimen of rituximab, bendamustine, and cytarabine (R–BAC). For these patients, following the R–BAC regimen, the ORR was 82.3% and the combined CR/unconfirmed CR rate was 55.1%. The median progression free survival (PFS) was 9.3 months, and the median OS was 12.2 months.[289]

[277] Kantar Health. CancerMPact® United States. September 2018, v1.2.

[278] Vose JM. Mantle cell lymphoma: 2017 update on diagnosis, risk-stratification, and clinical management. Am J Hematol. 2017;92(8):806–813.

[279] Ibrutinib USPI. Available from: *https://www.imbruvica.com/docs/librariesprovider7/default-document-library/prescribing_information.pdf.*

[280] Acalabrutinib USPI. Available from: *https://www.azpicentral.com/calquence/calquence.pdf#page=1.*

[281] Rule S, et al. Median 3.5-year follow-up of ibrutinib treatment in patients with relapsed/refractory Mantle Cell Lymphoma: A pooled analysis. *Blood* Dec. 2017;130(Suppl 1):151.

[282] Cheah CY, et al. Patients with mantle cell lymphoma failing ibrutinib are unlikely to respond to salvage chemotherapy and have poor outcomes. *Ann Oncol.* 2015;26(6):1175–9.

[283] Martin P, et al. Postibrutinib outcomes in patients with mantle cell lymphoma. *Blood.* 2016;127 (12):1559–63.

[284] DerSimonian R, Laird N. Meta-analysis in clinical trials. *Control Clin Trials.* 1986;7(3):177–88.

[285] Cheah CY, et al. Patients with mantle cell lymphoma failing ibrutinib are unlikely to respond to salvage chemotherapy and have poor outcomes. *Ann Oncol.* 2015;26(6):1175–9.

[286] Martin P, et al. Postibrutinib outcomes in patients with mantle cell lymphoma. *Blood.* 2016;127 (12):1559–63.

[287] Regny C, et al. Clinical efficacy of the RIBVD regimen for refractory/relapsed (r/r) Mantle Cell Lymphoma (MCL) patients: A retrospective study of the LYSA Group [Poster]. EHA; 2019 13–16 June; Amsterdam, Netherlands.

[288] Regny C, et al. Clinical efficacy of the RIBVD regimen for refractory/relapsed (r/r) Mantle Cell Lymphoma (MCL) patients: A retrospective study of the LYSA Group [Poster]. EHA; 2019 13–16 June; Amsterdam, Netherlands.

[289] McCulloch R, et al. R–BAC maintains high response rate in Mantle Cell Lymphoma following relapse on BTK inhibitor therapy [Abstract 3989]. ASH Annual Meeting; 2019 07–10 December; Orlando, FL.

The ZUMA–2 study of KTE–X19 is the only pivotal study of CAR T-cell therapy for r/r MCL. ZUMA–2 is a multicenter, open label, Phase 2 study which evaluated the safety and efficacy of KTE–X19 in patients with r/r MCL that relapsed or are refractory to prior therapy, including BTK inhibitors. Participants were required to have received at least 5 prior regimens of MCL treatment, which must have included anthracycline (or bendamustine containing chemotherapy), an anti-CD20 monoclonial anitibody and BTK inhibitor. The ZUMA–2 study included 68 subjects treated with KTE–X19. The safety analysis included a review of all 68 subjects, with the primary analysis of efficacy reviewing the first 60 subjects treated with KTE–X19. ZUMA–2 was conducted in 33 centers in the United States, France, Germany and the Netherlands. Of the 60 subjects in the primary analysis set, 59 were from U.S. sites. Of the 68 subjects in the safety analysis set, 62 were from U.S. sites. Among the 68 subjects, the median age was 65 years (range 38–79) and 54 subjects (84%) were male. Additionally, 58 of the subjects (85%) had stage IV of the disease and the subjects had a median of 3 prior therapies, with 55 or 81% of subjects having received ≥3 prior therapies. In addition, 43% had relapsed after a prior autologous stem cell transplant (ASCT); the remaining subjects had either relapsed after or were refractory to their last therapy for MCL.

The applicant initially submitted information from its interim analysis of ZUMA–2, which included 28 subjects treated with KTE–X19 who had the opportunity to be followed for 12 months at the time of the data cutoff (May 30, 2018). In supplemental information shared with CMS, which the applicant referred to as its primary analysis, all 60 subjects were followed for 6 months after the Week 4 disease assessment, and the 28 subjects from the interim analysis were followed for 24 months.

According to the applicant, because no effective standard therapy for subjects with r/r MCL who have progressed following a prior BTK inhibitor therapy exists, ZUMA–2 had no comparison arm. The applicant described how a historical control was the only ethical and feasible study design for patients with r/r MCL who had not responded to the most promising therapies available, including BTK inhibitors. Therefore, the historical controls consisted of two studies by Martin et al., (2016) and Cheah et al., (2015), and a meta-analysis of six studies, consisting of 255 subjects, discovered during a literature search.

According to the Martin et al. (2016), retrospective cohort study referenced by the applicant, the investigators-reported best response rate (RR) to ibrutinib was 55% (43% partial response [PR], 12% complete response [CR]), with 35% of patients having a best response of progressive disease. But among patients who received subsequent therapy, local clinicians reported that 13 patients (19%) achieved PR, and 5 (7%) achieved CR. The median overall survival (OS) following cessation of ibrutinib was 2.9 months (95% confidence interval [CI], 1.6–4.9). Of the 104 patients with data available, 73 underwent at least one additional line of currently available treatment after stopping ibrutinib with a median OS of 5.8 months (95% confidence interval [CI], 3.7–10.4).[290]

Also according to the Cheah et al. (2015), retrospective review study referenced by the applicant, they found that among the 31 patients who experienced disease progression following ibrutinib and underwent salvage therapy, the overall objective response rate (ORR) and complete response rate (CRR) was 32% and 19%, respectively. After a median follow-up of 10.7 (range 2.4–38.9) months from discontinuation of ibrutinib, the median OS among patients with disease progression was 8.4 months and the estimated one-year OS was 22.1% (95% CI 8.3% to 40.2%).[291]

To evaluate the effectiveness of KTE–X19, the applicant noted it used an ORR comparison of 25%, which was derived from the two aforementioned studies (Martin et al., and Cheah et al.) with patients with r/r MCL who progressed on the most predominantly prescribed BTK inhibitor, ibrutinib. The results of these two studies showed a median OS of 5.8 months after receiving at least 1 additional line of currently available therapy to treat r/r MCL. Those who did not receive salvage therapy had a median OS of 0.8 months.[292]

The applicant asserted that the interim analysis of ZUMA–2 demonstrated the efficacy of KTE–X19 in subjects (n = 28) with r/r MCL who were heavily pretreated. The interim analysis showed patients with an ORR of 86% (24/28 subjects; 95% CI: 67% to 96%), which was an increase compared to the pre-specified historical control ORR of 25% and the pooled ORR obtained through the meta-analysis of 28%.

Summary of Best Overall Response: KTE-X19 and Historical Control

Response Category	KTE-X19 (interim analysis of 28 subjects in ZUMA-2)	Historical Control (%)	Pooled ORR (%) (meta-analysis of 255 subjects across 6 studies)
	N (%)	%	(%)
Objective Responders (CR +PR) n (%) 95% Confidence Interval[a]	24 (86) 67,96		
Complete Response (CR) n (%)	16 (57)		
Partial Response (PR) n (%)	8 (29)	25	
Stable Disease n (%)	2 (7)	Not applicable	28
Progressive Disease n (%)	2 (7)		
Not Evaluable n (%)	0 (0)		23, 34

[290] *Op cit,* Martin.

[291] *Op cit,* Cheah.

[292] *Ibid.*

Based on the primary analysis of the 60 subjects included in the ZUMA–2 study, there was an ORR of 93% after a single dose of KTE–X19 (56 of 60 subjects with a 95% CI of 83.8%, 98.2%). The applicant reported that the complete response rate was 67% (40 of 60 subjects with a 95% CI of 53.3%, 78.3%). The applicant noted the ORR of 93% and CR 67% were observed across age groups (94% ages ≥65; 93% ages <65. And, of the 40 subjects achieving CR, 22 subjects were aged ≥65 and 18 were aged <65). The applicant highlighted that the ORR of 93% was significantly higher than the prespecified historical control rate of 25%. Furthermore, the applicant noted that among the 42 subjects who initially had a partial response (PR) or stable disease (SD), 24 subjects (57%) went on to achieve a CR after a median of 2.2 months (range: 1.8 to 8.3 months). Twenty-one subjects converted from PR to CR, and 3 subjects converted from SD to CR.

The primary analysis from ZUMA–2 showed that with a median follow-up time of 12.3 months, the median DOR was not reached following the KTE–X19 therapy and that this result was consistent across age groups. Kaplan-Meier estimates of the progression free survival (PFS) rates at 6 months and 12 months were 77.0% and 60.9%, respectively, and the median PFS was not reached with a median potential follow-up of 12.3 months (range: 7.0 to 32.3 months) (this analysis was provided by the applicant). Additionally, 57% of all patients and 78% of patients with a CR remained in remission (results consistent across age groups). Furthermore, as reported by the applicant, among the first 28 subjects studied as part of the interim analysis, 43% remained in continued remission without additional therapy at the follow-up period of 27 months (range, 25.3—32.3).

The ZUMA–2 primary analysis 6-month and 1-year survival rate was 86.7% and 83.2%, respectively. The applicant also conducted an additional analysis of OS among the first 28 subjects (ZUMA–2 interim analysis) who were treated with KTE–X19 and had a potential follow-up of ≥24 months. Among these subjects, the OS rate estimate at 24 months was 67.9% and the median OS was not reached. In comparison, the Cheah and et al. (2015) post-ibrutinib salvage therapy study reported a lower one-year survival rate of 22%. Additionally, among the subjects in CR at month 3 who had the opportunity to be followed to month 12, 90% remained in CR at month 12. The applicant contended that this statistic showcased that early responses to KTE–X19 are likely indicative of long-term remission after the single infusion of KTE–X19. Furthermore, the applicant suggested that a substantial number of patients with r/r MCL treated with KTE–X19 will achieve a CR, and that this suggests these patients will likely experience a long-term remission after a single infusion of KTE–X19. The applicant also noted that these results were consistent across age groups at the time of the primary data analysis cut-off (July 24, 2019). By contrast, the applicant noted that patients with r/r MCL who had prior BTK inhibitor treatment had CR rates ranging from 7–22%. Additionally, the applicant noted that the majority of patients on BTK inhibitor treatment go on to have progressive disease given that the responses achieved with currently available salvage therapies are short lived and have a DOR ranging from 3 to 5.8 months.[293] [294] [295] [296]

In regards to the safety and efficacy of KTE–X19, the applicant argued that the ZUMA–2 study demonstrated a positive benefit-risk of KTE–X19 over the current therapy options for patients with r/r MCL. The applicant stated that the toxicity profile that is associated with KTE–X19 therapy can be managed and that the KTE–X19 risk evaluation and mitigation strategies (REMS) will ensure that hospitals providing KTE–X19 therapy are certified so that all who prescribe, dispense, or administer KTE–X19 are aware of how to manage the risk of cytokine release syndrome (CRS) and neurologic events. However, the applicant notes that patients who were ≥65 years old showed a trend toward a higher incidence of Grade 3 or higher CRS compared to those ≤65 years old. (21% versus 7%). Additionally, all subjects in the ZUMA–2 primary analysis had at least 1 adverse event (AE), 99% of subjects had at least 1 AE that was Grade 3 or higher, and 68% of subjects had at least 1 serious adverse event (SAE). The most common Grade 3 or higher AEs were anemia and neutrophil count decreased (50% each) and WBC decreased (40%). Furthermore, CRS occurred in 62 of 68 (91%) subjects in the ZUMA–2 safety analysis. Of these, 8 subjects (12%) had worst Grade 3 CRS, and 2 subjects (3%) had worst Grade 4 CRS. No subject had Grade 5 CRS, according to the applicant. Furthermore, according the applicant, the most common CRS symptoms of any grade were pyrexia, hypotension, and hypoxia. The most common Grade 3 or higher CRS symptoms were hypotension (15 subjects, 24%), hypoxia (12 subjects, 19%), and pyrexia (7 subjects, 11%). No patient in the ZUMA–2 study treated with KTE–X19 died from CRS.

The applicant mentioned that 43 of the 68 patients (63%) in the ZUMA–2 study also experienced forms of neurologic events. Of these, 15 subjects (22%) had a worst Grade 3 neurologic event, and 6 subjects (9%) had a worst Grade 4 neurologic event. Twenty-two subjects (32%) had serious neurologic events, however, the applicant noted no subject had a Grade 5 neurologic event. Of these, the most common neurologic events of any grade were tremor, encephalopathy, and confusional state. The most common Grade 3 or higher neurologic events were encephalopathy (13 subjects, 19%), confusional state (8 subjects, 12%), and aphasia (3 subjects, 4%). Compared with subjects who were <65 years of age, subjects who were ≥65 years of age showed a trend toward a higher incidence of Grade 3 or higher neurologic events (36% versus 24%). The applicant noted that these neurologic events resolved for all but 6 subjects and that among those whose neurologic events had resolved, the median duration was 12 days. Additionally, no patient died from neurologic events.

Overall, ZUMA–2 primary results showed that at the time of the analysis cutoff (July 2019), 16 of 68 subjects (24%) had died; 4 deaths occurred >30 days through 3 months after infusion of KTE–X19 and 12 deaths occurred ≥3 months after infusion of KTE–X19. Fourteen of the 16 subjects died as a result of progressive disease and two of the 16 subjects died due to AEs other than disease progression (Grade 5 AE of staphylococcal bacteremia and Grade 5 AE of organizing pneumonia).

Although the applicant asserted that KTE–X19 represents a substantial clinical improvement compared to other currently available treatments, we are concerned with the generalizability of the findings from ZUMA–2 to the general Medicare population. We note that 85% of ZUMA–2 participants had stage IV disease development and that

[293] Kochenderfer JN, et al. Lymphoma Remissions Caused by Anti-CD19 Chimeric Antigen Receptor T Cells Are Associated With High Serum Interleukin-15 Levels. *J Clin Oncol.* 2017a;35(16):1803–13.

[294] Kochenderfer JN, et al. Long-Duration Complete Remissions of Diffuse Large B Cell Lymphoma after Anti-CD19 Chimeric Antigen Receptor T Cell Therapy. *Mol Ther.* 2017b;25(10):2245–53.

[295] Gupta S, et al. Recommendations for the design, optimization, and qualification of cell-based assays used for the detection of neutralizing antibody responses elicited to biological therapeutics. *Journal of Immunological Methods.* 2007;321(1–2):1–18.

[296] Davila ML, et al. Efficacy and toxicity management of 19–28z CAR T cell therapy in B cell acute lymphoblastic leukemia. *Sci Transl Med.* 2014;6(224):224ra25.

this therapy may demonstrate a benefit to a sicker patient population. However, we are concerned about whether the population of the ZUMA–2 study mirrors the characteristics of the Medicare population and whether the study included patients that had a similar severity of disease as would be common within the Medicare population.

The literature search performed by the applicant included a total of 255 subjects, across 6 studies, and the ZUMA–2 study included 68 subjects studied in the primary analysis. We are concerned with the relatively small combined sample size from the literature search and ZUMA–2 study performed by the applicant. We also note that the applicant stated that it closely communicated with FDA in the development of the ZUMA–2 study, including in the development of the sample size, but we remain concerned about whether the ZUMA–2 study results support a determination of substantial clinical improvement given the small sample size. Although the applicant's analysis of the ZUMA–2 study concluded that KTE–X19 offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, we are concerned as to whether the sample size and research presented in this application support extrapolating these results across the Medicare population.

We are also concerned that there has not been a direct study completed comparing outcomes of patients with r/r MCL treatment with KTE–X19 and BTK inhibitors. According to the applicant, ZUMA–2 remains the only study to evaluate patient outcomes after receiving KTE–X19 for the treatment of r/r MCL, but this study does not include a direct comparison to other existing therapies for r/r MCL. Despite there being no standard of second-line care for r/r MCL patients that failed on previous therapies, according to the applicant, a BTK inhibitor reflects the best currently available therapy for treating r/r MCL.[297]

While the ZUMA–2 primary analysis 6 month and one-year survival rate was 86.7% and 83.2%, respectively, we are concerned that a longer term analysis of this population is not available to evaluate the overall survival and mortality data. We note that the applicant did conduct an additional analysis of OS among the first 28 subjects (ZUMA–2 interim analysis) which showed an OS rate estimate at 24 months of 67.9% while the median OS was not reached. Additionally, the applicant referenced that all subjects in the ZUMA–2 primary analysis had at least 1 adverse event, and that throughout the course of the ZUMA–2 study, 16 deaths were recorded. However, while the applicant noted only 2 of these 16 deaths were related to adverse events, we remain concerned that further analysis may be needed to evaluate the safety of KTE–X19 and the longer term effects of the CRS and neurological events associated with the KTE–X19 therapy.

We are inviting public comments on whether KTE–X19 meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for the KTE–X19 or at the New Technology Town Hall meeting.

j. Lisocabtagene Maraleucel (Liso-cel)

Juno Therapeutics, a Bristol-Myers Squibb Company, submitted an application for new technology add-on payment for FY 2021 for lisocabtagene maraleucel (Liso-cel). Liso-cel is an investigational, CD19-directed, autologous chimeric antigen receptor (CAR) T-cell immunotherapy that is comprised of individually formulated CD8 (killer) and CD4 (helper) CAR T-cells that the applicant anticipates to be indicated for the treatment of adult patients with relapsed or refractory (r/r) large B-cell lymphoma after at least two prior therapies. According to the National Comprehensive Cancer Network, Diffuse Large B-cell lymphoma (DLBCL) is the most common type of Non-Hodgkin's Lymphoma (NHL) in the U.S. and worldwide, accounting for nearly 30% of newly diagnosed cases of B-cell NHL in U.S.[298] DLBCL is characterized by spreading of B-cells through the body that have either arrived de novo or by the transformation from indolent lymphoma.

According to the applicant, the standard-of-care, first-line immune-chemotherapy for DLBCL includes regimens such as cyclophosphamide, doxorubicin, vincristine, and prednisone plus rituximab (R–CHOP).[299] These regimens result in long-lasting remission in more than 50% of patients.[300] However, approximately 10% to 15% of patients will have primary refractory disease (that is, nonresponse or relapse within three months of first-line therapy), and an additional 20% to 25% will relapse following an initial response to therapy.[301] Patients with relapses of aggressive B-cell lymphomas are believed to have a poor prognosis because of potential treatment resistance and rapid tumor growth, with only about 30% to 40% responding to salvage chemotherapy (for example, R–ICE, DHAP, or Gem-ox) followed by high-dose therapy and autologous stem cell transplantation for patients demonstrating chemotherapy-sensitive disease.[302] Among patients eligible to undergo autologous stem cell transplantation (ASCT), only 50% will achieve a remission adequate to proceed to ASCT, and approximately 50% will relapse after transplantation.[303] The applicant also noted that transplant eligibility is also restricted based on age and tolerance to high dose chemotherapy and thus excludes a moderate subset of patients with r/r DLBCL.

Additionally, the applicant explained that the available therapies for 3L+ large B-cell lymphoma include the following:

- CD19-directed genetically modified autologous CAR T-cell immunotherapy axicabtagene ciloleucel (YESCARTA®), approved in October 2017 for the treatment of adult patients with r/r large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma (FL).[304]

[297] Campo E, Rule S. Mantle cell lymphoma: Evolving management strategies. *Blood.* 2015;125(1):48–55.

[298] Ferlay J, Colombet M, Soerjomataram, et al., Estimating the global cancer incidence and mortality in 2018: GLOBOCAN sources and methods, Int J Cancer. 144: 1941–1953 (Ferlay, 2019); NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas V. 5.2019. © National Comprehensive Cancer Network, Inc. 2019 (NCCN, 2019).

[299] Coiffier, Bertrand et al., Long-term outcome of patients in the LNH–98.5 trial, the first randomized study comparing rituximab-CHOP to standard CHOP chemotherapy in DLBCL patients: A study by Group d'Etudes des Lymphomes de l'Adulte, blood 2010 116: 2040–2045. (Coiffier, 2010).

[300] *Ibid.*

[301] *Ibid.*

[302] Crump M, Neelapu SS, Farooq U, et al., Outcomes in refractory diffuse large B-cell lymphoma: results from the international SCHOLAR–1 study, Blood. 2017; 130(16): 1800–1808 (Crump, 2017); Cunningham D, Hawkes EA, Jack A, et al. Rituximab plus cyclophosphamide, doxorubicin, vincristine, and prednisolone in patients with newly diagnosed diffuse large B-cell non-Hodgkin lymphoma: A phase 3 comparison of dose intensification with 14-day versus 21-day cycles Lancet. 2013; 381: 1817–1826 (Cunningham, 2013).

[303] *Ibid.*

[304] YESCARTA®'s approval was based on a single arm study (ZUMA–1) demonstrating an IRC-

Continued

• CAR T-cell therapy tisagenlecluecel (KYMRIAH®), approved in May 2018, for the treatment of adult patients with r/r large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL not otherwise specified, high grade B-cell lymphoma, and DLBCL arising from FL.[305]

• Programmed death receptor-1 (PD–1)-blocking antibody—(KEYTRUDA®), approved in 2018, for the treatment of adult and pediatric patients with refractory primary mediastinal B-cell lymphoma (PMBCL), or who have relapsed after two or more prior lines of therapy.[306]

• CD79b-directed antibody-drug conjugate polatuzumab vedotin (POLIVY®), in combination with bendamustine and rituximab, approved in 2019, for the treatment of adult patients with r/r DLBCL, not otherwise specified, after at least two prior therapies.

According to the applicant, despite the availability of these therapies, r/r large B-cell lymphoma remains a major cause of morbidity and mortality due to the aggressive disease course. The applicant noted that the safety profiles of these therapies exclude many r/r large B-cell lymphoma patients from being able to undergo treatment with these therapies.[307]

With respect to the newness criterion, the applicant submitted a BLA for Liso-cel in October 2019, however, as of the time of the development of this proposed rule, had not received FDA approval. Liso-cel was granted Breakthrough Therapy Designation (BTD) on December 15, 2016 and Regenerative Medicine Advanced Therapy (RMAT) designation on October 20, 2017, for the treatment of patients with r/r aggressive large B-cell NHL, including DLBCL, not otherwise specified (DLBCL NOS; de novo or transformed from indolent lymphoma), primary mediastinal B-cell lymphoma (PMBCL), or follicular lymphoma Grade 3B (FL3B)). We note that the applicant submitted a request for approval for a unique ICD–10–PCS procedure code for the administration of Liso-cel beginning in FY 2021. We note that procedures involving the CAR T-cell therapies previously approved for new technology add-on payments (KYMRIAH® and YESCARTA® therapies) are reported using the following ICD–10–PCS procedure codes: XW033C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3); and XW043C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3). Under the current coding system, cases involving the use of Liso-cel would be coded using ICD–10–PCS XW033C3 and XW043C3, which are currently grouped to MS–DRG 016. As discussed in section II.D.2.b. of the preamble of this proposed rule, effective for discharges occurring in FY 2021, we are proposing to assign cases reporting ICD–10–PCS procedure codes XW033C3 or XW043C3 to a proposed new MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy), which would include cases reporting the use of Liso-Cel, if approved and finalized. While we note the applicant has submitted a request for approval for a unique ICD–10–PCS code to describe the use of Liso-cel, beginning in FY 2021, any applicable finalized codes describing the use of Liso-cel will be addressed in the final rule.

As previously discussed, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant described two ways in which it believes the mechanism of action for Liso-cel differs from previously approved therapies for DLBCL. First, the applicant described the therapy as being comprised of individually formulated cryopreserved patient-specific helper (CD4) and killer (CD8) CAR T-cells in suspension that are administered as a defined composition of CAR-positive viable T-cells (from individually formulated CD8 and CD4 components). The applicant stated that the therapy involves a different mechanism of action from other CAR T-cell therapies because the CD4 and CD8 T-cells are purified and cultured separately to maintain compositional control of each cell type. Furthermore, during culture, each cell type is separately modified to have the CAR on the cell surface, expanded and quantified, and frozen in two separate cell suspensions. The applicant then described how Liso-cel is infused with the same target dose of CD4 and CD8 CAR T-cells for every patient. The applicant asserted that because Liso-cel controls the same dosage for both CD4 and CD8, it differs from other CAR T-cell therapies for DLBCL and could potentially provide for higher safety and efficacy; the applicant stated that CAR T-cell therapies that do not control for CD8 CAR T-cell dosage have demonstrated higher rates of severe and life-threatening toxicities, such as cytokine release syndrome (CRS) and neurotoxicity (NT).

The second feature the applicant described as distinguishing Liso-cel's mechanism of action from existing CD19-directed CAR T-cell therapies was the presence of an EGFRt cell surface tag. The applicant explained that the EGFRt cell surface tag could hypothetically be targeted for CAR T-cell clearance by separately administering cetuximab, a monoclonal antibody. According to the applicant, if the patient was separately administered cetuximab, the presence of the EGFRt cell surface tag within Liso-cel would allow cetuximba to bind to the CAR T-cells and clear the cells from the patient. The applicant highlighted studies that showed that persistent functional CD19-directed CAR T-cells in patients caused sustained depletion of a patient's normal B-cells that expressed CD19, resulting in hypogammaglobulinemia and an increased risk of life-threatening or chronic infections.[308] The applicant further explained that such prolonged low levels of normal B-cells could place a patient at risk of life-threatening or chronic infections. According to the applicant, the ability to deplete CAR T-cells, via the administration of cetuximab, when a patient achieves a long-term remission could hypothetically allow recovery of normal B-cells and potentially reduce the risk of life-threatening or chronic infections. The applicant noted that experiments in a laboratory setting showed that targeting EGFRt with the monoclonal antibody cetuximab eliminated CAR T-cells expressing the EGFRt marker, which resulted in long-term reversal of B-cell aplasia in mice.[309] However, the

assessed ORR of 72%, CR of 51%, and an estimated median DOR of 9.2 months in 101 subjects included in the modified intent-to-treat (mITT population).

[305] KYMRIAH®'s approval was based on a single-arm study (JULIET) demonstrating an ORR of 50% and a CR rate of 32% in 68 efficacy-evaluable subjects. A median DOR was not reached with a median follow-up of 9.4 months.

[306] KEYTRUDA is not recommended for treatment of patients with PMBCL who require urgent cytoreductive therapy. Keytruda USPI (2019).

[307] Smith SD, Reddy P, Sokolova A, et al., Eligibility for CAR T-cell therapy: An analysis of selection criteria and survival outcomes in chemorefractory DLBCL, Am. J. Hematol. 2019; E119: 1–4 (Smith, 2019).

[308] Kalos M, Levine BL, Porter DL, et al., T Cells with Chimeric Antigen Receptors Have Potent Antitumor Effects and Can Establish Memory in Patients with Advanced Leukemia, Sci Transl Med. 2011; 3(95): 1–21 (Kalos, 2011).

[309] Paszkiewicz PJ, Frable SP, Srivastava S, et al., Targeted antibody-mediated depletion of murine

applicant noted that this mechanism of CAR T-cell clearance, via administration of cetuximab and EGFRt cell surface tags/markers, has not been tested in humans nor in other patients treated with Liso-cel.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant acknowledged that Liso-cel would likely map to the same MS–DRG as other existing CAR T-cell therapies, which are currently assigned to MS–DRG 016. The applicant also referenced a request made by it and other CAR T-cell therapy manufacturers to create a new MS–DRG specifically for CAR T-cell therapies. The applicant also acknowledged that in previous rulemaking CMS stated that all CAR T-cell therapies would be assigned to MS–DRG 016, Autologous Bone Marrow Transplant with CC/MCC while CMS continues to study the issue. As previously noted and further discussed in section II.D.2.b. of the preamble of this proposed rule, we are proposing to assign CAR T-cell therapy cases to a new MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy) effective for discharges occurring in FY 2021.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, according to the applicant, Liso-cel fills an unmet need in the treatment of large B-cell lymphoma because Liso-cel would be indicated as a third-line treatment option for patients with r/r DLBCL, who cannot be treated with existing CAR T-cell therapies. The applicant asserted that Liso-cel would be able to treat these patients that present with uncommon subtypes of DLBCL including, PMBCL, FL3B, and DLBCL transformed from indolent lymphoma from other follicular lymphoma, elderly patients (≥65 years old), patients with secondary CNS involvement by lymphoma, and those with moderate renal or cardiac comorbidities. The applicant asserted that these patient populations were excluded from registrational trials for YESCARTA® and KYMRIAH®, and therefore represent an unmet patient need. Regarding newness, we are concerned as to whether a differing production and/or dosage represents a different mechanism of action as compared to previously FDA-approved CAR T-cell therapies. We are also concerned about whether the existence of an EGFRt cell surface tag equates to a new mechanism of action given that in order to activate this cell surface tag, an additional medication, cetuximab, which targets the CAR T-cells for clearance, would be needed. We also express concern that, based on our understanding, the presence of the EGFRt cell surface tag is a potential way to treat an adverse event of the Liso-cel therapy and is not critical to the way the drug treats the underlying disease. We note that the applicant referenced that while this EGFRt cell surface tag is included within the Liso-cel compound, it remains dormant without activation by cetuximab. Finally, the applicant noted that Liso-cel has been shown safe and effective for patient populations excluded from registrational trials for YESCARTA® and KYMRIAH®, including patients with uncommon subtypes of large B-cell lymphoma, including PMBCL, FL3B, and DLBCL transformed from indolent lymphoma other than FL, elderly patients (≥65 years old), patients with secondary CNS involvement by lymphoma and those with moderate renal or cardiac comorbidities.[310] We note that the FDA label for YESCARTA® and KYMRIAH® does not appear to specifically exclude these patient populations or NHL subtypes. As such, it is unclear whether Liso-cel would in fact treat a patient population different from other CAR T-cell therapies that treat patients with DLBCL. Additionally, as previously discussed, we are proposing to assign cases involving the use of Liso-cel to the same MS–DRG as other CAR T-cell therapies previously approved for new technology add-on payments. We refer readers to section II.D.2.b. of the preamble of this proposed rule for discussion of our proposal to create a new MS–DRG 018 for CAR T-cell therapies which, if finalized, would include cases reporting the use Liso-cel.

We are inviting public comments on whether Liso-cel is substantially similar to other technologies and whether Liso-cel meets the newness criterion.

With regard to the cost criterion, the applicant searched the FY 2018 MedPAR claims data file to identify potential cases representing patients who may be eligible for treatment using Liso-cel. The applicant identified claims that reported an ICD–10–CM diagnosis code of: C83.30 (DLBCL, unspecified site); C83.31 (DLBCL, lymph nodes of head, face and neck); C83.32 (DLBCL, intrathoracic lymph nodes); C83.33 (DLBCL, intra-abdominal lymph nodes); C83.34 (DLBCL, lymph nodes of axilla and upper limb); C83.35 (DLBCL, lymph nodes of inquinal region and lower limb); C83.36 (DLBCL, intrapelvic lymph nodes); C83.37 (DLBCL, spleen); C83.38 (DLBCL, lymph nodes of multiple sites); or C83.39 (DLBCL, extranodal and solid organ sites). However, the applicant noted that the aforementioned ICD–10–CM codes do not differentiate r/r patients from the broader DLBCL population. A clinical literature search completed by the applicant found that the r/r population makes up one-third of the DLBCL population, but since r/r patients typically have higher inpatient costs, the applicant selected one-third of the total identified cases with the highest total charges. The applicant also identified potential cases where the claim contained either ICD–10–PCS code XW033C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3) or XW043C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3) in addition to the DLBCL diagnosis codes. The applicant found a total of 1,798 cases reporting either one of the previously identified diagnosis codes or ICD–10–PCS code XW033C3 or XW043C3, mapped to 22 MS–DRGs.

The applicant noted that this analysis was based on charges from claims in the FY 2018 MedPAR final rule file and were selected based on the presence of one diagnosis code and one procedure code as previously discussed. As discussed previously, because clinical data suggests that about 33% of DLBCL patients are r/r and those patients have higher inpatient costs than non r/r DLBCL patients, the applicant analyzed the top third costliest discharges, but also diversified this analysis by randomly selecting 20% of the remaining cases to account for the variety of treatment options for patients with DLBCL. The applicant stated that the use of Liso-cel's therapy would replace chemotherapy or other drug therapies, including other CAR T-cell therapies. Because of this, the applicant stated it removed all charges in the drug cost center since it was not possible to differentiate between different drugs on inpatient claims. The standardized charges per case were then calculated using the 2018 IPPS final rule Impact file and the two-year inflation factor of 11.1% (1.11100) was applied. The applicant noted that the cost of Liso-cel had not yet been determined at the time of application. Therefore, without

CD19 CAR T cells permanently reverses B cell aplasia, J Clin Invest. 2016; 126(11): 4262–4272 (Paszkiewicz, 2016).

[310] Lisocabtagene maraleucel Biologics License Application (BLA).

considering the charges for Liso-cel, based on the FY 2020 IPPS/LTCH PPS final rule correction notice data file thresholds for FY 2021, the final inflated average case-weighted standardized charge per case was $117,726, which is lower than the MS–DRG 016 average case-weighted threshold of $170,573. However, we note that the applicant expects the cost of Liso-cel to be higher than the new technology add-on payment threshold amount for MS–DRG 016. Therefore, the applicant stated that Liso-cel met the cost criterion.

As we have discussed in prior rulemaking with regard to the potential creation of a new MS–DRG for CAR–T cell therapies (83 FR 41172), if a new MS–DRG were to be created, then consistent with section 1886(d)(5)(K)(ix) of the Act, there may no longer be a need for a new technology add-on payment under section 1886(d)(5)(K)(ii)(III) of the Act. Section 1886(d)(5)(K)(ix) of the Act requires that, before establishing any add-on payment for a new medical service or technology, the Secretary shall seek to identify one or more DRGs associated with the new technology, based on similar clinical or anatomical characteristics and the costs of the technology and assign the new technology into a DRG where the average costs of care most closely approximate the costs of care using the new technology. As discussed in previous rulemaking (71 FR 47996), no add-on payment will be made if the new technology is assigned to a DRG that most closely approximates its costs.

As noted previously and discussed in section II.D.2.b of the preamble of this proposed rule, we are proposing to create proposed new MS–DRG 018 for cases reporting the use of CAR T-cell therapies beginning in FY 2021. We also refer readers to section II.G.5.i. of the preamble of this proposed rule, regarding the new technology add-on payment application for KTE–X19, for a complete discussion of our proposal that, effective for FY 2022, for applications for new technology add-on payments and for previously approved technologies that may continue to receive new technology add-on payments, the proposed threshold for a proposed new MS–DRG for the upcoming fiscal year would be used to evaluate the cost criterion for technologies that would be assigned to a proposed new MS–DRG. As also discussed in section II.G.5.i. of this proposed rule, in light of the significant variance in the threshold amount for the proposed new MS–DRG for cases reporting CAR T-cell therapies, we are also proposing to apply this policy when evaluating the CAR T-cell therapy technologies for FY 2021 new technology add-on payments. The application of this proposed policy for FY 2021 would include the new FY 2021 CAR T-cell therapy applications and, as discussed in section II.G.4.a. of the preamble of this proposed rule, those CAR T-cell therapy technologies previously approved for new technology add-on payments.

As such, we are proposing to evaluate whether Liso-cel meets the cost criterion using the proposed new MS–DRG 018 threshold amount of $1,237,393. As previously mentioned, without considering the cost of the technology, the final inflated average case-weighted standardized charge per case is $117,726. However, we now have cases involving the use of CAR T-cell therapy within the FY 2019 MedPAR data that we believe may reflect cases that could be eligible for Liso-cel or which can be used to approximate the charges for Liso-cel to estimate the average standardized charge per case for purposes of this proposed rule. This charge information from the FY 2019 MedPAR data can be found in the FY 2021 Proposed Before Outliers Removed (BOR) File (available on the CMS website) for Version 38 of the MS–DRGs. Based on information from the FY 2021 Proposed BOR File for Version 38 of the MS–DRGs, the standardized charge per case for MS–DRG 018 is $913,224. The average case-weighted threshold amount based on the proposed new MS–DRG 018 is $1,237,393. Because this estimated average case-weighted standardized charge per case does not exceed the average case-weighted threshold amount for proposed MS–DRG 018, we do not believe that the technology would meet the cost criterion. We note that this analysis is based on CMS data. The applicant conducted its own analysis as previously described that did not include the cost of the technology. We welcome additional information from the applicant regarding the cost of Liso-cel to inform our determination for the final rule regarding whether the applicant meets the cost criterion based on the applicant's cost analysis.

We invite public comment on our proposal to evaluate the cost criterion for Liso-cel using the proposed threshold amount for proposed new MS–DRG 018 and whether Liso-cel meets the cost criterion based on this proposal.

With respect to the substantial clinical improvement criterion, the applicant asserted that Liso-cel represents a substantial clinical improvement over existing technologies because it offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments. The applicant stated that Liso-cel fills an unmet need in the treatment of patients with large B-cell lymphoma, including DLBCL, and provides an immunotherapy treatment option for r/r DLBCL patients who cannot be treated with existing CAR T-cell therapies. To support this statement, the applicant described what it considered were important populations that were excluded from the registrational trials for YESCARTA® and KYMRIAH® (such as renal and cardiac insufficiency, limited marrow reserve, central nervous system (CNS) involvement by lymphoma, and relapse after allogeneic hematopoietic stem cell transplant (HSCT)). The applicant stated that these trials also excluded certain large B-cell lymphoma subtypes such as DLBCL transformed from indolent lymphomas other than FL, PMBCL, and follicular lymphoma Grade 3B (FL3B), but that these excluded patient populations were included in the registrational trial for Liso-cel.[311] The applicant referenced that the use of Liso-cel had been studied for these patients, and was shown to be safe and resulted in durable responses, including for patients with uncommon subtypes of large B-cell lymphoma, including PMBCL, FL3B, and DLBCL transformed from indolent lymphoma other than FL, elderly patients (≥65 years old), patients with secondary CNS involvement by lymphoma, and those with moderate renal or cardiac comorbidities.[312] According to the applicant, the registrational trials for YESCARTA® and KYMRIAH® also did not include adequate numbers of Medicare eligible subjects,[313] [314] [315] and therefore the applicant asserted that Liso-cel represents a substantial clinical improvement over these existing therapies because it has been shown to have a benefit to a meaningful number of Medicare beneficiaries. To support this assertion, the applicant stated that 41% of the subjects treated with Liso-cel were over the age of 65 years and a similar safety and efficacy profile was seen for this patient cohort as compared

[311] Neelapu, 2017; Schuster SJ, Bishop MR, Tam CS, et al., Tisagenlecleucel in Adult Relapsed or Refractory Diffuse Large B-Cell Lymphoma, N Engl J Med. 2019; 380(1): 45–56 (Schuster, 2019).

[312] Lisocabtagene maraleucel Biologics License Application (BLA).

[313] Neelapu, 2017.

[314] Schuster, 2019.

[315] Yescarta USPI (2019); Kymriah USPI (2018).

to a younger cohort.[316] The applicant provided further detail regarding these assertions, referencing the results of Phase I and Phase II studies.

The applicant shared the results of the Phase I TRANSCEND NHL 001 trial, which was a prospective, single arm, multicenter study of lisocabtagene maraleucel in patients with relapsed/refractory aggressive B-cell NHL. The applicant noted that TRANSCEND NHL 001 included subjects with the average age of 63 years with 111 subjects (41%) over 65 years of age and 27 (10%) subjects older than 75 years of age. These patients also failed previous therapies. Of the total number of subjects studied (efficacy: n=256; safety: n=269), 137 subjects (51%) had DLBCL, 60 (22%) had DLBCL transformed from FL, 18 (7%) had DLBCL transformed other indolent lymphomas, 36 patients (13%) had high grade lymphoma, 15 (6%) had PMBCL and 3 (1%) had FL3B.[317] Additionally, the applicant explained that TRANSCEND NHL 001 was more inclusive, compared to the registrational trials for KYMRIAH® and YESCARTA®, of Medicare aged patients with comorbidities and NHL disease subtypes seen in the real world presentation of the disease. To support this, the applicant referenced that within this study, between 40% to 50% of subjects studied had cardiac ejection fraction, 3% had secondary CNS lymphoma, 51 patients (19%) had a creatinine clearance between 30–60 mL/min and 39 patients (14.6%) had grade ≥3 cytopenias. Furthermore, the applicant noted that 51 patients (19%) had decreased renal function and 13 patients (4.9%) had decreased cardiac function. The applicant stated that the TRANSCEND NHL 001 study showcased that the patient population treated during the study better reflected the real world large B-cell lymphoma patient population, a population that the applicant asserted included NHL subtypes not studied or approved for treatment with currently approved or conditionally approved agents, while providing similar safety and efficacy. The applicant contended that these high-unmet need large B-cell lymphoma subsets included patients with DLBCL transformed from rare indolent lymphomas other than FL, patients with FL3B, patients 65 years of age and older, as well as patients with moderate comorbidities of renal and cardiac insufficiency.

The applicant further explained that Liso-cel provided improved effectiveness as compared to existing therapies. Patients with aggressive large B-cell NHL who have failed at least 2 prior therapies or SCT are treated with combinations of agents or monotherapy based on institutional preferences, but there is no standard of care for salvage therapies beyond first treatment therapy.[318] The applicant noted that commonly used salvage therapies (non-CAR T-cell therapies) for relapsed, large B-cell lymphoma demonstrated objective response rates (ORRs) in the range of 12% to 46% and complete response (CR) rates of 6% to 38%. Among the patients who did achieve a response, the median duration of response (DOR) ranges from approximately 6 to 17 months and median overall survival was generally less than 12 months.[319] Comparatively, TRANSCEND NHL 001, which provided subjects with Liso-cel, met its primary endpoint of Independent Review Committee (IRC)-assessed ORR in adult patients with r/r large lymphoma after at least 2 prior therapies, as reported by the applicant. In the 256 efficacy evaluable patients, the ORR was 73% (95% confidence interval (CI]): 67.0% to 78.3%), and the CR rate was 53% (95% CI: 46.6% to 59.2%). With a median follow-up of 10.8 months, the median DOR per IRC assessment was 13.3 months and the median DOR for CR was not reached. By comparison, the applicant summarized that YESCARTA®, as demonstrated in the Phase I–II ZUMA–1 study (see the FY 2019 IPPS/LTCH PPS final rule 83 FR 41295 for a description of this study), had an ORR of 72.0% (95% confidence interval (CI: 62.0% to 81.0%). Also, according to the applicant, KYMRIAH®, as demonstrated by the Phase II JULIET study (see the FY 2019 IPPS/LTCH PPS final rule 83 FR 41293 for a description of this study), had an ORR of 50.0% (95% confidence interval (CI: 38.0% to 62.0%). The applicant contended that the results for Liso-cel (ORR of 73% (95% confidence interval (CI]): 67.0% to 78.3%), and the CR rate of 53% (95% CI: 46.6% to 59.2%)) were observed across all subgroups tested, including elderly subjects, those with high burden disease or high baseline inflammatory biomarkers, those requiring anti-lymphoma therapy for disease control, as well as rare patient populations with a high unmet medical need (for example, PMBCL, DLBCL transformed from indolent lymphoma other than FL, and FL3B). The applicant contended that this data supports that Liso-cel demonstrates comparable or superior effectiveness compared to existing therapies for patients with r/r large B-cell NHL.[320] [321]

Furthermore, the applicant stated that Liso-cel had an improved safety profile in comparison to YESCARTA® and KYMRIAH®. The applicant stated that both of these FDA-approved CAR T-cell therapies had higher rates of toxicity as compared to Liso-cel. In the TRANSCEND NHL 001 registrational study (n=268), 42% and 2% of subjects developed all-grade and Grade >3 CRS, respectively, and 30% and 10% developed all-grade and Grade >3 NT. The applicant compared these results to the results of the JULIET study as found in KYMRIAH's® prescribing information and summarized that KYMRIAH® had higher rates of all-grade and Grade >3 CRS (74% and 23%, respectively) and all-grade and Grade >3 NT (58% and 18%, respectively). The applicant provided the same comparison of the toxicity results of Liso-cel to the results showcased in the ZUMA–1 study featuring YESCARTA® as found in YESCARTA®'s prescribing information and summarized that YESCARTA® had higher rates of all-grade and Grade >3 CRS (94% and 13%, respectively) and all-grade and Grade >3 NT (87% and 31%, respectively).[322] [323]

After reviewing the information submitted by the applicant as part of its

[316] Lisocabtagene maraleucel Biologics License Application (BLA).

[317] Ibid.

[318] NCCN, 2019.

[319] Czuczman MS, Davies A, Linton KM, et al., A Phase ⅔ Multicenter, Randomized Study Comparing the Efficacy and Safety of Lenalidomide Versus Investigator's Choice in Relapsed/Refractory DLBCL, Blood. 2014; 124: 628 (Czuczman, 2014); Jacobsen ED, Sharman JP, Oki Y, et al., Brentuximab vedotin demonstrates objective responses in a phase 2 study of relapsed/refractory DLBCL with variable CD30 expression, Blood. 2015; 125(9): 1394–1402 (Jacobsen, 2015); Nagle SJ, Woo K, Schuster SJ, et al., Outcomes of patients with relapsed/refractory diffuse large B-cell lymphoma with progression of lymphoma after autologous stem cell transplantation in the rituximab era, Am. J. Hematol. 2013; 88: 890–894 (Nagle, 2013); Pettengell R, Coiffier B, Narayanan G, et al., Pixantrone dimaleate versus other chemotherapeutic agents as a single-agent salvage treatment in patients with relapsed or refractory aggressive non-Hodgkin lymphoma: a phase 3, multicenter, open-label, randomised trial, Lancet Oncol. 2012; 13: 696–706 (Pettengell, 2012); Rigacci L, Puccini B, Cortelazzo S, et al., Bendamustine with or without rituximab for the treatment of heavily pretreated non-Hodgkin's lymphoma patients, Ann Hematol. 2012; 91: 1013–1022 (Rigacci, 2012); Van Den Neste E, Schmitz N, Mounier N, et al., Outcome of patients with relapsed diffuse large B-cell lymphoma who fail second-line salvage regimens in the International CORAL study, Bone Marrow Transplantation. 2016; 51: 51–57 (Van Den Neste, 2016); Wang M, Fowler N, Wagner-Bartak N, et al., Oral lenalidomide with rituximab in relapsed or refractory diffuse large cell, follicular and transformed lymphoma: a phase II clinical trial, Leukemia. 2013; 27: 1902–1909 (Wang, 2013).

[320] YESCARTA® USPI (2019).

[321] KYMRIAH® USPI (2018).

[322] YESCARTA® USPI (2019).

[323] KYMRIAH® USPI (2018).

FY 2021 new technology add-on payment application, we are concerned that no published studies directly comparing Liso-cel and the two currently available CAR T-cell therapies for r/r DLBCL, YESCARTA® and KYMRIAH®, were provided. Additionally, we are concerned with the lack of long-term data supporting the effectiveness and efficacy of Liso-cel and whether the lack of long-term data may limit the generalizability of the findings from the TRANSCEND NHL 001 study to the general Medicare population. While there is no direct comparison study of Liso-cel, YESCARTA® and KYMRIAH®, the applicant does provide a comparison of the ORR, CR, PR and DOR across all three CAR T-cell therapies. While we note that Liso-cel does appear to provide an improved ORR, CR, PR, and DOR compared to the other FDA-approved CAR T-cell therapies based on the data presented by the applicant, we further note that these differences appear to be small in magnitude, between 1–2% for the ORR, CR, and PR. Without a direct comparison of outcomes between these therapies, we are concerned as to whether these differences translate to clinically meaningful differences or improvements. Liso-cel appears to demonstrate similar patient outcomes to that of YESCARTA® and we question whether the TRANSCEND NHL 001 study is evidence that Liso-cel is a more effective therapy to treat DLBCL over existing CAR T-cell therapies. Additionally, as previously discussed, the applicant noted that Liso-cel has been shown safe and effective for patient populations excluded from registrational trials for YESCARTA® and KYMRIAH®. However, it is unclear whether this suggests that Liso-cel is a treatment option for patients who cannot be treated with these existing CAR–T cell therapies, given that the FDA label for YESCARTA® and KYMRIAH® appears to not specifically exclude these patient populations. Finally, we are concerned that the use of the EGFRt cell surface tag was not activated in patients receiving Liso-cel to study the impact of clearing these CAR T-cells after remission and that this feature has not yet been tested on humans or in conjunction with patients treated with Liso-cel. We express concern regarding the safety and efficacy of this feature given its lack of testing.

We are inviting public comments on whether Liso-cel meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for Liso-cel or at the New Technology Town Hall meeting.

k. Soliris

Alexion, Inc, submitted an application for new technology add-on payments for Soliris® (eculizumab) for FY 2021. Soliris® is approved for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.

According to the applicant, NMOSD is a rare and severe condition that attacks the central nervous system without warning. The applicant explained that NMOSD attacks, also referred to as relapses, can cause progressive and irreversible damage to the brain, optic nerve and spinal cord, which may lead to long-term disability, and in some instances, the damage may result in death. According to the applicant, the serious nature of an NMOSD relapse frequently requires inpatient hospitalization and treatment should be initiated as quickly as possible.

According to the applicant, in patients with AQP4 antibody-positive NMOSD, the body's own immune system can turn against itself to produce auto-antibodies against AQP4, a protein on certain cells in the eyes, brain and spinal cord that are critical for the survival of nerve cells. The applicant explained that the binding of these anti-AQP4 auto-antibodies activates the complement cascade, another part of the immune system.

According to the applicant, complement activation by anti-AQP4 auto-antibodies is one of the primary causes of NMOSD. The applicant explained that formation of membrane attack complex (MAC) is the end product of the activated complement system which is directly responsible for the damage to astrocytes leading to astrocytopathy (astrocyte death) and ensuing neurologic damage associated with NMOSD and relapses. According to the applicant, the primary goal of NMOSD treatment is to prevent these relapses, which over time lead to irreversible neurologic damage.

According to the applicant, Soliris® is a first-in-class complement inhibitor that works by selectively inhibiting the complement system, a central part of the immune system involved in inflammatory processes, pathogen elimination, activation of the adaptive immune response, and maintenance of homeostasis. The applicant explained that the complement system distinguishes between healthy host cells, cell debris, apoptotic cells, and external pathogens. The applicant further explained that the complement system triggers a modulated immune response, and functions through a combination of effector proteins, receptors, and regulators. The applicant asserted that when the complement system detects a threat, an initial protease is activated. This protease (either alone or in a complex) then cleaves its target, which in turn becomes active and starts to cleave the next target in the chain, and so on, leading to a cascade.

Per the applicant, initial activation of the complement system occurs via three different pathways, which all ultimately lead to the formation of the membrane attack complex (MAC) and release of the anaphylatoxins: (1) The classical pathway is activated by antibody-antigen complexes; (2) The alternative pathway is activated at a constant low level via ''tick-over'' (spontaneous hydrolysis) of Complement component 3 (C3), a protein of the immune system; (3) The lectin pathway is activated by carbohydrates frequently found on the surface of microbes. According to the applicant, all pathways of complement activation result in the formation of C3 convertase (''proximal complement''), and converge at the cleavage of C5 leading to the generation of C5a and C5b by the C5 convertase enzyme complexes (''Terminal complement''). The applicant explained that C3 is the most abundant complement protein in plasma, occurring at a concentration of 1.2 mg/mL and C3 cleavage products bridge the innate and the adaptive immune systems. The applicant also explained that C3a acts as an anaphylatoxin and is a mediator of inflammatory processes and C3b opsonizes the surface of recognized pathogens and facilitates phagocytosis and binds C3 convertase to form C5 convertase. The applicant also explained that C5 convertase cleaves C5 into C5a and C5b; C5a is chemotactic agent and anaphylatoxin, causing leukocyte activation, endothelial cell activation, and proinflammatory and prothrombotic effects.

According to the applicant, imbalance between complement activation and regulation leads to host tissue damage, and congenital deficiencies in the complement system can lead to an increased susceptibility to infection. The applicant explained that the complement system is also associated with the pathogenesis of non-infectious diseases such as chronic inflammation, autoimmune diseases, thrombotic

microangiopathy, transplant rejection reactions, ischemic, neurodegenerative age-associated diseases, and cancer. According to the applicant, the complement system is also recognized as important in the antibody-mediated autoimmune disease AQP4 antibody-positive NMOSD. The applicant stated that Soliris® is the first and only FDA approved treatment for adult patients with NMOSD who are AQP4 antibody-positive that is proven to reduce the risk of relapse.

The incidence of NMOSD in the United States is 0.7/100,000 while the prevalence is 3.9/100,000 population.[324] The median onset of NMOSD is 39 years of age and 83 percent of cases are female.[325] [326] NMOSD was commonly misdiagnosed as multiple sclerosis (MS) in the past.[327] According to the applicant, at least two-thirds of NMOSD cases are associated with aquaporin-4 antibodies (AQP4-IgG) and complement-mediated damage to the central nervous system.

According to the applicant, Soliris® is administered via an IV infusion by a healthcare professional. The applicant explained that for adult patients with neuromyelitis optica spectrum disorder, Soliris® therapy consists of 900 mg weekly for the first 4 weeks, followed by 1200 mg for the fifth dose 1 week later, then 1200 mg every 2 weeks thereafter. According to the applicant, Soliris® should be administered at the recommended dosage regimen time points, or within 2 days of these time points. The applicant also explained that for adult and pediatric patients with NMOSD, supplemental dosing of Soliris® is required in the setting of concomitant plasmapheresis or plasma exchange, or fresh frozen plasma infusion (PE/PI).

The applicant explained that Soliris® has a boxed warning for risk of serious meningococcal infections. According to the applicant, life-threatening and fatal meningococcal infections have rarely occurred in patients treated with Soliris® and can be mitigated with proper vaccination. The applicant explained that by blocking the terminal complement system, Soliris® increases the risk of meningococcal and encapsulated bacterial infection. According to the applicant, all the patients in a pivotal trial received meningococcal vaccination, and no cases of meningococcal infection were reported. The applicant also noted that Soliris® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) and under the Soliris® REMS, prescribers must enroll in the program.

With respect to the newness criterion, the FDA approved Soliris® for the indication of treatment of NMOSD in adult patients who are AQP4 antibody positive on June 27, 2019. Soliris® was first approved by the FDA on March 19, 2007 for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis, followed by approvals for the treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement mediated thrombotic microangiopathy, and for an efficacy supplement to add the indication of treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. The applicant has applied for new technology add-on payments for use of Soliris® only for the indication of treatment of NMOSD in adult patients who are AQP4 antibody positive. The applicant stated that the FDA granted Soliris® Orphan Drug Designation for the treatment of neuromyelitis optica on June 24, 2014. Additionally, the applicant stated that Soliris® was filed as a supplemental biologics license application (sBLA; BLA125166/S–431) for the treatment of NMOSD in adult patients who are AQP4 antibody positive, which the FDA assigned Priority Review status.

According to the applicant, patients with NMOSD are currently identified by ICD–10–CM diagnosis code: G36.0 Neuromyelitis optica (Devic's syndrome). The applicant also noted that there is currently no ICD–10–PCS procedure code to specifically identify NMOSD cases where Soliris® is used. We note that the applicant has submitted a request for approval for a unique ICD–10–PCS procedure code for the administration of the Soliris® beginning in FY 2021.

As stated previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and, therefore, would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, according to the applicant, Soliris® is the only treatment for NMOSD that works by specifically inhibiting the complement cascade as described previously. According to the applicant, Soliris® is the only FDA approved treatment for NMOSD, although several off-label products are used to treat relapse prevention in NMOSD. As mentioned previously, the applicant explained that the formation of the membrane attack complex (MAC) is the end product of the activated complement system which is directly responsible for the damage to astrocytes leading to astrocytopathy (astrocyte death) and the ensuing neurologic damage associated with NMOSD and relapses.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that cases involving the administration of Soliris® will likely be assigned to the same MS–DRGs as other therapies are that are currently used but not indicated to treat NMOSD. These therapies that are used off-label include axiothiprine, rituximab, low-dose steroids (prednisone), mycophenolate, methotrexate, mitoxantrone, cyclophosphamide, tacrolimus, tocilizumab, cyclosporin A, and plasma exchange. As stated previously, the applicant asserted that Soliris® is the first approved treatment for NMOSD in adult patients who are AQP4 antibody positive.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant maintained that, although Soliris® will be treating the same disease and patient population as currently available therapies, it will improve the treatment of NMOSD as there were previously no FDA labeled treatments. As stated previously, the applicant asserted that Soliris® is the first approved treatment for NMOSD in adult patients who are AQP4 antibody positive.

In summary, the applicant asserted that Soliris® meets the newness criterion because it is the only treatment for NMOSD that works by specifically inhibiting the complement cascade. We are inviting public comments on whether Soliris® is substantially similar to other technologies and whether Soliris® meets the newness criterion.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that the technology meets the cost criterion. The applicant searched claims in the FY 2018 MedPAR final rule dataset

[324] Flanagan EP, et al., ''Epidemiology of aquaporin-4 autoimmunity and neuromyelitis optica spectrum,'' *Ann Neurol,* 2016, vol. 79(5), pp. 775–783.

[325] Bukhari W, et al., ''Incidence and prevalence of NMOSD in Australia and New Zealand,'' *J Neurol Neurosurg Psychiatry,* 2017, vol. 88(8), pp. 632–638.

[326] Wingerchuk DM, et al., ''The spectrum of neuromyelitis optica,'' *Lancet Neurol,* 2007, vol. 6, pp. 805–815.

[327] Jarius S, et al., ''Contrasting disease patterns in seropositive and seronegative neuromyelitis optica: A multicentre study of 175 patients,'' *J Neuroinflammation,* 2012, vol. 9, pp. 14.

reporting an ICD–10–CM diagnosis code of G36.0. This search identified 1,151 cases primarily spanning 14 MS–DRGs. According to the applicant, cases representing patients who may be eligible for treatment with Soliris® for NMOSD would most likely map to MS–DRGs 058, 059 and 060 (Multiple Sclerosis and Cerebellar Ataxia with MCC, with CC and without CC/MCC, respectively)—the family of MS–DRGs for multiple sclerosis & cerebellar ataxia. According to the applicant, these three MS–DRGs were three of the top four MS–DRGs by volume to which cases reporting a diagnosis code G36.0 were assigned, and together these MS–DRGs accounted for about 32 percent of the 1,151 originally identified cases reporting a diagnosis code G36.0. Consequently, the applicant limited its analysis to the 376 cases that grouped to these three MS–DRGs (058, 059 and 060).

The applicant performed its cost analysis based on the 376 claims assigned to MS–DRGs 058, 059 and 060. The applicant first removed charges for other technologies. According to the applicant, Soliris® would replace other drug therapies, such as azathioprine, methotrexate, and rituximab, among others. Because it is generally not possible to differentiate between different drugs on inpatient claims, the applicant removed all charges in the drug cost center. The applicant also removed all charges from the blood cost center, because Soliris® will replace plasma exchange procedures. Lastly, the applicant removed an additional $12,000 of cost for the plasma exchange procedural costs, based on an internal analysis of the average cost of plasma exchange. To convert these costs to charges, the applicant used the ''other services'' national average cost-to-charge ratio (0.346). According to the applicant, this was likely an overestimate of the charges that would be replaced by using Soliris®.

After removing charges for the prior technology to be replaced, the applicant standardized the charges. The applicant then used the 2-year inflation factor of 11.1 percent, as published in the FY 2020 IPPS final rule (84 FR 42629), to inflate the charges from FY 2018 to FY 2020. To determine the charges for Soliris®, the applicant assumed hospitals would use the inverse of the national average cost to charge ratio for pharmacy costs (0.189) from the FY 2020 IPPS/LTCH PPS final rule to mark-up charges.

Based on the aforementioned analysis, the applicant computed a final inflated average case-weighted standardized charge per case of $72,940, as compared to a calculated threshold value of $44,420. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion. We are inviting public comments on whether Soliris® meets the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant asserted that Soliris® represents a substantial clinical improvement over existing technologies because it significantly improves clinical outcomes relative to services or technologies previously available, as demonstrated by the applicant's clinical data and patient outcomes, such as the prevention of relapses in patients with NMOSD.

The applicant provided a randomized, controlled trial in support of its claims of reduction of first-adjudicated on-trial relapse with Soliris® (PREVENT).[328] The PREVENT study enrolled 143 adults who were randomly assigned in a 2:1 ratio to receive intravenous eculizumab (at a dose of 900 mg weekly for the first four doses starting on day 1, followed by 1200 mg every 2 weeks starting at week 4) or a matched placebo. The continued use of stable-dose immunosuppressive therapy was permitted. The primary endpoint studied was first adjudicated relapse. Secondary outcomes included the adjudicated annualized relapse rate, quality-of-life measures, and the score on the Expanded Disability Status Scale (EDSS), which ranges from 0 (no disability) to 10 (death). Adjudicated relapses occurred in 3 of 96 patients (3 percent) in the Soliris® group and 20 of 47 (43 percent) in the placebo group (hazard ratio, 0.06; 95 percent confidence interval [CI], 0.02 to 0.20; P<0.001). The adjudicated annualized relapse rate was 0.02 in the eculizumab group and 0.35 in the placebo group (rate ratio, 0.04; 95 percent CI, 0.01 to 0.15; P<0.001). The applicant also explained that 97.9 percent of patients on Soliris® remained NMOSD relapse free at 48 weeks, 96.4 percent at 96 weeks and 96.4 percent at 144 weeks. There was no significant between-group difference in measures of disability progression. The mean change in the EDSS score was −0.18 in the eculizumab group and 0.12 in the placebo group (least-squares mean difference, −0.29; 95% CI, −0.59 to 0.01).

The applicant also submitted a poster presentation of post hoc efficacy analyses in pre-specified subgroups from the PREVENT study.[329] Pre-specified subgroup summaries for time to first adjudicated relapse were based on immunosuppressive therapies (IST) use (five subgroups for concomitant IST use; two subgroups according to whether or not rituximab was previously used), geographic region, age, sex, race and randomization stratum. Time to first adjudicated relapse was increased with eculizumab compared with placebo in all subgroups analyzed. Significant treatment effects were observed in all subgroups for IST use, region, age, sex and race, except for the smallest subgroups in which the differences were similar to the others but did not reach nominal significance owing to small sizes (patients using other ISTs, n = 7; Black/African American patients, n = 17, among whom none of the nine patients receiving eculizumab experienced a relapse), and in patients from the Americas owing to the performance of the placebo arm. In patients who had received rituximab more than 3 months before the study, the adjudicated relapse risk reduction was 90.7 percent with eculizumab compared with placebo (p = 0.0055). The proportion of patients who were relapse-free at week 48 was consistently higher with eculizumab than with placebo in all pre-specified IST subgroups.

As stated previously the applicant asserted that Soliris® represents a substantial clinical improvement over existing technologies because it reduces relapses in patients with NMOSD. The applicant explained that the PREVENT study demonstrated several endpoints. The applicant explained that Soliris® reduced first adjudicated on-trial relapse with eculizumab in comparison to placebo with a 94 percent relative risk reduction (Hazard Ratio, 0.006; 95% CI, 0.02–0.20). The applicant also explained that 97.9 percent of Soliris® patients were relapse free at 48 weeks, compared to 63.2 percent for the placebo group. The applicant further noted that in a subgroup of patients utilizing monotherapy (patients on eculizumab or placebo only, without

[328] Pittock, S.J., Berthele, A., Fujihara, K., Kim, H.J., Levy, M., Palace, J., Nakashima, I., Terzi, M., Totolyan, N., Viswanathan, S., Wang, K.C., Pace, A., Futita, K.P., Armstrong, R., Wingerchuk, D.M., ''Eculizumab in Aquaporin-4–Positive Neuromyelitis Optica Spectrum Disorder.'' *N Engl J Med.,* 2019, vol 381(7), pp., 614–625.

[329] Pittock, S.J., Berthele, A., Fujihara, K., Kim, H.J., Levy, M., Palace, J., Nakashima, I., Terzi, M., Totolyan, N., Viswanathan, S., Wang, K.C., Pace, A., Futita, K.P., Yountz, M., Armstrong, R., Wingerchuk, D.M., ''Subgroup analyses from the phase 3 PREVENT study in patients with aquaporin-4 antibody-positive neuromyelitis optica spectrum disorder,'' September 11–13, 2019, Poster presentation at ECTRIMS, Stockholm, Sweden.

concomitant immunosuppressant agents), 100 percent of Soliris® patients were relapse free at 48 weeks compared to 60.6 percent for placebo. The applicant also explained that in the PREVENT subgroup analysis presented as a poster, the treatment effect was observed regardless of whether it was used as a monotherapy or with concomitant ISTs (corticosteroids alone, azathioprine, mycophenolate mofetil); previous IST use (including rituximab); geographical region; age; sex; and race.

The applicant also explained that the Soliris® U.S. Prescribing Information contains the following information on resource utilization in the applicant's phase III trials (corticosteroid use, plasma exchange treatment, and hospitalizations): Compared to placebo-treated patients, the PREVENT study showed that Soliris®-treated patients had reduced annualized rates of (1) hospitalizations (0.04 for Soliris® versus 0.31 for placebo), (2) of corticosteroid administration to treat acute relapses (0.07 for Soliris® versus 0.42 for placebo), and (3) of plasma exchange treatments (0.02 for Soliris® versus 0.19 for placebo). The applicant explained that annualized rates were calculated by dividing the total number of on-trial relapses requiring acute treatment during the study period for all patients by the number of patient-years in the study period.

After reviewing the information submitted by the applicant as part of its FY 2021 new technology add-on payment application for Soliris, we are concerned that the applicant provided only one study in support of its assertions of substantial clinical improvement, which is the PREVENT trial, with additional supporting documents all based on the same trial. We note that the study compared Soliris to placebo but that there was no comparison of Soliris to currently available treatments to gauge real world efficacy, nor was there information about how these current treatments work and why they are ineffective. Furthermore, in the PREVENT trial, the applicant did not provide the dosage amounts for the patients on continuing medication in addition to placebo or Soliris. It is not clear to us if the patients receiving Soliris had higher dosages of continuing medications than those in the placebo group. We would be interested in more information about the dosage amounts in the treatment and control groups in the PREVENT trial. We are inviting public comment on whether Soliris® technology meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for Soliris® or at the New Technology Town Hall meeting.

l. SpineJack® System

Stryker, Inc., submitted an application for new technology add-on payments for the SpineJack® Expansion Kit (hereinafter referred to as the SpineJack® system) for FY 2021. The applicant described the SpineJack® system as an implantable fracture reduction system, which is indicated for use in the reduction of painful osteoporotic vertebral compression fractures (VCFs) and is intended to be used in combination with Stryker VertaPlex and VertaPlex High Viscosity (HV) bone cement.

The applicant explained that the SpineJack® system is designed to be implanted into a collapsed vertebral body (VB) via a percutaneous transpedicular approach under fluoroscopic guidance. According to the applicant, once in place, the intravertebral implants are expanded to mechanically restore VB height and maintain the restoration. The applicant explained that the implants remain within the VB and, together with the delivered bone cement, stabilize the restoration, provide pain relief and improve patient mobility. According to the applicant, the SpineJack® system further reduces the risk of future adjacent level fractures (ALFs).[330]

The applicant explained that the SpineJack® system is available in three sizes (4.2, 5.0 and 5.8 mm), and implant size selection is based upon the internal cortical diameter of the pedicle. According to the SpineJack® system Instructions for Use, the use of two implants is recommended to treat a fractured VB. According to the applicant, multiple VBs can also be treated in the same operative procedure as required.

The applicant explained that using a bilateral transpedicular approach, the SpineJack® implants are inserted into the fractured VB. The applicant stated that the implants are then progressively expanded though actuation of an implant tube that pulls the two ends of the implant towards each other in situ to mechanically restore VB height. The applicant explained that the mechanical working system of the implant allows for a progressive and controlled reduction of the vertebral fracture.[331] The applicant stated that when expanded, each SpineJack® implant exerts a lifting pressure on the fracture through a mechanism that may be likened to the action of a scissor car jack, and that the longitudinal compression on the implant causes it to open in a craniocaudal direction. The applicant explained that the implant is locked into the desired expanded position as determined and controlled by the treating physician.[332]

The applicant further explained that once the desired expansion has been obtained, polymethylmethacrylate (PMMA) bone cement is injected at low pressure into and around the implant to stabilize the restored vertebra, which leads the implant to become encapsulated with the delivered bone cement. According to the applicant, restoration of the anatomy and stabilization of the fracture results in pain relief as well as improved mobility for the patient.[333]

According to the applicant, osteoporosis is one of the most common bone diseases worldwide that disproportionately affects aging individuals. The applicant explained that in 2010, approximately 54 million Americans aged 50 years or older had osteoporosis or low bone mass,[334] which resulted in more than 2 million osteoporotic fragility fractures in that year alone.[335] The applicant stated it has been estimated that more than 700,000 VCFs occur each year in the United States (U.S.),[336] and of these VCFs, about 70,000 result in hospital admissions with an average length of stay of 8 days per patient.[337]

[330] Noriega, D., et al., ''A prospective, international, randomized, noninferiority study comparing an implantable titanium vertebral augmentation device versus balloon kyphoplasty in the reduction of vertebral compression fractures (SAKOS study),'' *The Spine Journal,* November 2019, vol 19(11), pp. 1782–1795.

[331] Vanni D., et al., ''Third-generation percutaneous vertebral augmentation systems,'' *J. Spine Surg.,* 2016, vol. 2(1), pp. 13–20.

[332] Noriega D. et al., ''Clinical Performance and Safety of 108 SpineJack Implantations: 1-Year Results of a Prospective Multicentre Single-Arm Registry Study,'' *BioMed Res. Int.,* 2015, vol. 173872.

[333] Ibid.

[334] National Osteoporosis Foundation. (2019). What is osteoporosis and what causes it? Available from: *https://www.nof.org/patients/what-is-osteoporosis/*.

[335] King A and Fiorentino D. ''Medicare payment cuts for osteoporosis testing reduced use despite tests' benefit in reducing fractures.'' *Health Affairs (Millwood),* 2011, vol. 30(12), pp. 2362–2370.

[336] Riggs B and Melton L. ''The worldwide problem of osteoporosis: Insights afforded by epidemiology.'' *Bone,* 1995, vol. 17(Suppl 5), pp. 505–511.

[337] Siemionow K and Lieberman I. ''Vertebral augmentation in osteoporotic and osteolytic

Continued

Furthermore, the applicant noted that in the first year after a painful vertebral fracture, patients have been found to require primary care services at a rate 14 times greater than the general population.[338] The applicant explained that medical costs attributed to VCFs in the U.S. exceeded $1 billion in 2005 and are predicted to surpass $1.6 billion by 2025.[339]

The applicant explained that osteoporotic VCFs occur when the vertebral body (VB) of the spine collapses and can result in chronic disabling pain, excessive kyphosis, loss of functional capability, decreased physical activity and reduced quality of life. The applicant stated that as the spinal deformity progresses, it reduces the volume of the thoracic and abdominal cavities, which may lead to crowding of internal organs. The applicant noted that the crowding of internal organs may cause impaired pulmonary function, abdominal protuberance, early satiety and weight loss. The applicant indicated that other complications may include bloating, distention, constipation, bowel obstruction, and respiratory disturbances, such as pneumonia, atelectasis, reduced forced vital capacity and reduced forced expiratory volume in 1 second.

The applicant stated that if VB collapse is >50 percent of the initial height, segmental instability will ensue. As a result, the applicant explained that adjacent levels of the VB must support the additional load and this increased strain on the adjacent levels may lead to additional VCFs. Furthermore, the applicant summarized that VCFs also lead to significant increases in morbidity and mortality risk among elderly patients, as evidenced by a 2015 study by Edidin et al., in which researchers investigated the morbidity and mortality of patients with a newly diagnosed VCF (n = 1,038,956) between 2005 to 2009 in the U.S. Medicare population. For the osteoporotic VCF subgroup, the adjusted 4-year mortality was 70 percent higher in the conservatively managed group than in the balloon kyphoplasty procedures (BKP)-treated group, and 17 percent lower in the BKP group than in the vertebroplasty (VP) group. According to the applicant, when evaluating treatment options for osteoporotic VCFs, one of the main goals of treatment is to restore the load bearing bone fracture to its normal height and stabilize the mechanics of the spine by transferring the adjacent level pressure loads across the entire fractured vertebra and in this way, the intraspinal disc pressure is restored and the risk of adjacent level fractures (ALFs) is reduced.

The applicant explained that treatment of osteoporotic VCFs in older adults most often begins with conservative care, which includes bed rest, back bracing, physical therapy and/or analgesic medications for pain control. According to the applicant, for those patients that do not respond to conservative treatment and continue to have inadequate pain relief or pain that substantially impacts quality of life, vertebral augmentation (VA) procedures may be indicated. The applicant explained that VP and BKP are two minimally invasive percutaneous VA procedures that are most often used in the treatment of osteoporotic VCFs and another VA treatment option includes the use of a spiral coiled implant made from polyetheretherketone (PEEK), which is part of the Kiva® system.

According to the applicant, among the treatment options available, BKP is the most commonly performed procedure and the current gold standard of care for VA treatment. The applicant stated that it is estimated that approximately 73 percent of all vertebral augmentation procedures performed in the United States between 2005 and 2010 were BKP.[340] According to the applicant, the utilization of the Kiva® system is relatively low in the U.S. and volume information was not available in current market research data.[341]

The applicant stated that VA treatment with VP may alleviate pain, but it cannot restore VB height or correct spinal deformity. The applicant stated that BKP attempts to restore VB height, but the temporary correction obtained cannot be sustained over the long-term. The applicant stated that the Kiva® implant attempts to mechanically restore VB height, but it has not demonstrated superiority to BKP for this clinical outcome.[342]

With respect to the newness criterion, the SpineJack® Expansion Kit received FDA 510(k) clearance on August 30, 2018, based on a determination of substantial equivalence to a legally marketed predicate device. The applicant explained that although the SpineJack® Expansion Kit received FDA 510(k) clearance on August 30, 2018, due to the time required to prepare for supply and distribution channels, it was not available on the U.S. market until October 11, 2018. As we discussed previously, the SpineJack® Expansion Kit is indicated for use in the reduction of painful osteoporotic VCFs and is intended to be used in combination with Stryker VertaPlex and VertaPlex High Viscosity (HV) bone cements. According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify the SpineJack® system. We note that the applicant submitted a request for approval for a unique ICD–10–PCS procedure code for the implantation of the SpineJack® system beginning in FY 2021.

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and therefore would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or similar mechanism of action to achieve a therapeutic outcome, according to the applicant, there are several factors that highlight the different mechanism of action in treating osteoporotic VCFs with the SpineJack® system compared to other BKP implants to reduce the incidence of ALFs and improve midline VB height restoration. According to the applicant, these differences include implant construction, mechanism of action, bilateral implant load support and >500 Newtons (N) of lift pressure.

The applicant described the SpineJack® system as including two cylindrical implants constructed from Titanium-6-Aluminum-4-Vanadium (Ti6Al4V) with availability in three sizes 4.2 mm (12.5 mm expanded), 5.0 mm (17 mm expanded) and 5.8 mm (20 mm expanded).

According to the applicant, the SpineJack® implant exerts lifting pressure on the fracture through a mechanism that may be likened to the action of a scissor car jack. The applicant explained that following the insertion of the implant into the vertebral body (VB), it is progressively expanded though actuation of an implant tube that pulls the two ends of the implant towards each other and the longitudinal compression on the implant causes it to open in a craniocaudal direction. According to the

fractures: Current Opinion in Supportive and Palliative Care.'' 2009, vol. 3(3), pp. 219–225.

[338] Wong C and McGirt M. ''Vertebral compression fractures: A review of current management and multimodal therapy.'' *Journal of Multidisciplinary Healthcare,* 2013, vol 6, pp. 205–214.

[339] Burge R et al. ''Incidence and economic burden of osteoporosis-related fractures in the United States: 2005–2025.'' *Journal of Bone and Mineral Research.* 2007, vol 22(3), pp. 465–475.

[340] Goz V et al. ''Vertebroplasty and kyphoplasty: National outcomes and trends in utilization from 2005 through 2010.'' *The Spine Journal.* 2015, vol. 15(5), pp. 959–965.

[341] Lin M. ''Minimally invasive vertebral compression fracture treatments. *Medtech 360, Market Insights, Millennium Research Group.* 2019.

[342] Ibid.

applicant, the force generated by the bilateral SpineJack® implants varies according to implant size, ranging from 500–1,000 Newtons for fracture reduction and superior endplate lift. In addition, the applicant explained that the SpineJack® implant provides symmetric, broad load support under the fractured endplate and spinal column which differentiates the mechanism of action from BKPs.[343]

The applicant stated that the SpineJack® implant is uniquely constructed from a titanium alloy, which the applicant claims allows for plastic deformation when it encounters the hard cortical bone of the endplate yet still provides the lift force required to restore midline VB height in the fractured vertebra. The applicant stated that the SpineJack® system notably contains a self-locking security mechanism that restricts further expansion of the device when extreme load forces are concentrated on the implant. As a result, the applicant asserted that this feature significantly reduces the risk of vertebral endplate breakage while it further allows functional recovery of the injured disc.[344]

According to the applicant, the expansion of the SpineJack® implants creates a preferential direction of flow for the bone cement; PMMA bone cement is deployed from the center of the implant into the VB. The applicant stated that when two implants are symmetrically positioned in the VB, this allows for a more homogenous spread of PMMA bone cement. The applicant asserted that the interdigitation of bone cement creates a broad supporting ring under the endplate, which is essential to confer stability to the VB.

The applicant explained that the SpineJack® implants provide symmetric, broad load support for osteoporotic vertebral collapse, which is based upon precise placement of bilateral ''struts'' that are encased in PMMA bone cement, whereas BKP and vertebroplasty (VP) do not provide structural support via an implanted device. The applicant explained that the inflatable balloon tamps utilized in BKP are not made from titanium and are not a permanent implant. According to the applicant, the balloon tamps are constructed from thermoplastic polyurethane, which have limited load bearing capacity. The applicant noted that although the balloon tamps are expanded within the VB to create a cavity for bone cement, they do not remain in place and are removed before the procedure is completed. The applicant explained that partial lift to the VB is obtained during inflation, resulting in kyphotic deformity correction and partial gains in anterior VB height restoration, but inflatable balloon tamps are deflated prior to removal so some of the VB height restoration obtained is lost upon removal of the bone tamps. According to the applicant, BKP utilizes the placement of PMMA bone cement to stabilize the fracture and does not include an implant that remains within the VB to maintain fracture reduction and midline VB height restoration.

According to the applicant the Kiva® system is constructed of a nitinol coil and PEEK–OPTIMA sheath, with sizes including a 4-loop implant (12 mm expanded) and a 5-loop implant (15 mm expanded) and unlike the SpineJack® system, is not made of titanium and does not include a locking scissor jack design. The applicant stated that the specific mechanism of action for the Kiva® system is different from the SpineJack® system. The applicant explained that during the procedure that involves implanting the Kiva® system, nitinol coils are inserted into the VB to form a cylindrical columnar cavity. The applicant stated that the PEEK–OPTIMA is then placed over the nitinol coil. The applicant explained that the nitinol coil is removed from the VB and the PEEK material is filled with PMMA bone cement. The applicant stated that the deployment of 5 coils equates to a maximum of height of 15 mm. The applicant stated that the lifting direction of the Kiva implant is caudate and unidirectional. According to the applicant, in the KAST (Kiva Safety and Effectiveness Trial) pivotal study, it was reported that osteoporotic VCF patients treated with the Kiva® system had an average of 2.6 coils deployed.[345] Additionally, in a biomechanical comparison conducted for the Kiva® system and BKP using a loading cycle of 200–500 Newtons in osteoporotic human cadaver spine segments filled with bone cement, there were no statistically significant differences observed between the two procedures for VB height restoration, stiffness at high or low loads, or displacement under compression.[346]

The applicant summarized the differences and similarities of the SpineJack®, BKP, and PEEK coiled implant as follows: (1) With respect to construction, SpineJack® is made of Titanium-6-Aluminum-4-Vanadium compared to thermoplastic polyurethanes for BKP and nitinol and PEEK for the PEEK coiled implant; (2) with respect to mechanism of action, the SpineJack® uses a locking scissor jack encapsulated in PMMA bone cement compared to hydrodynamic cavity creation and PMMA cavity filler for BKP and coil cavity creation and PEEK implant filled with PMMA bone cement for the PEEK coiled implant; (3) with respect to plastic deformation, SpineJack® and BKP allow for plastic deformation while the PEEK coiled implant does not; (4) with respect to craniocaudal expansion, SpineJack® allows for craniocaudal expansion, whereas BKP and the PEEK coiled implant do not; (5) with respect to bilateral load support, SpineJack® provides bilateral load support whereas BKP and the PEEK coiled implant do not; and (6) with respect to lift pressure of >500 N, SpineJack® provides lift pressure of >500 N whereas BKP and the PEEK coiled implant do not. The applicant summarized that the SpineJack® system is uniquely constructed and utilizes a different mechanism of action than BKP, which is the gold standard of treatment for osteoporotic VCFs, and that the construction and mechanism of action of the SpineJack® system is further differentiated when compared with the PEEK coiled implant.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant did not specify whether it believed cases involving the SpineJack® system would be assigned to the same MS–DRG as existing technology. However, we note that the MS–DRGs the applicant included in its cost analysis were the same MS–DRGs to which cases involving BKP procedures are typically assigned.

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, the applicant did not specifically address whether the technology meets this criterion. However, the applicant generally

[343] Jacobson R et al. ''Re-expansion of osteoporotic compression fractures using bilateral SpineJack implants: Early clinical experience and biomechanical considerations.'' *Cureus.* 2019, vol 11(4), e4572.

[344] Vanni D et al. ''Third-generation percutaneous vertebral augmentation systems.'' *Journal of Spine Surgery.* 2016, vol 2(1), pp. 13–20.

[345] Tutton S et al. KAST Study: The Kiva system as a vertebral augmentation treatment—a safety and effectiveness trial: A randomized, noninferiority trial comparing the Kiva system with balloon kyphoplasty in treatment of osteoporotic vertebral compression fractures. *Spine.* 2015; 40(12):865–875.

[346] Wilson D et al. An ex vivo biomechanical comparison of a novel vertebral compression fracture treatment system to kyphoplasty. *Clinical Biomechanics.* 2012; 27(4):346–353.

summarized the disease state that the technology treats as osteoporotic VCFs, and described other treatment options for osteoporotic VCFs as including VP, BKP and the PEEK coiled implant.

In summary, the applicant asserted that the SpineJack® system is not substantially similar to any existing technology because it utilizes a different mechanism of action, when compared to existing technologies, to achieve a therapeutic outcome.

We are inviting public comments on whether the SpineJack® system is substantially similar to other currently available technologies and whether the SpineJack® system meets the newness criterion.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that the technology meets the cost criterion. The applicant searched the FY 2018 MedPAR file for inpatient hospital claims that reported the following ICD–10–PCS procedure codes: 0PS43ZZ (Reposition thoracic vertebra, percutaneous approach) in combination with 0PU43JZ (Supplement thoracic vertebra with synthetic substitute, percutaneous approach) and 0QS03ZZ (Reposition lumbar vertebra, percutaneous approach) in combination with 0QU03JZ (Supplement lumbar vertebra with synthetic substitute, percutaneous approach). According to the applicant, the results included cases involving BKP procedures.

This resulted in 15,352 cases spanning approximately 130 MS–DRGs, with approximately 77 percent of those cases (n=11,841) mapping to the following top 6 MS–DRGs:

MS-DRG	MS-DRG Title
MS–DRG 477	Biopsies of Musculoskeletal System and Connective Tissue with MCC
MS–DRG 478	Biopsies of Musculoskeletal System and Connective Tissue with CC
MS–DRG 479	Biopsies of Musculoskeletal System and Connective Tissue without CC/MCC
MS-DRG 515	Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC
MS–DRG 516	Other Musculoskeletal System and Connective Tissue O.R. Procedures with CC
MS-DRG 517	Other Musculoskeletal System and Connective Tissue O.R. Procedures without CC/MCC

The applicant performed two separate analyses with regard to the cost criterion, one based on 100 percent of the claims reporting the specified ICD–10–PCS procedure codes, and the second based on the 77 percent of claims mapping to the top six MS–DRGs.

The applicant used the following methodology for both analyses. The applicant first removed the charges for the prior technology being replaced by SpineJack®. The applicant explained that it estimated charges associated with the prior technology as 50 percent of the charges associated with the category Medical Surgical Supply Charge Amount (which included revenue centers 027x). The applicant stated that use of the SpineJack® system would replace some but not all of the device charges included in these claims, as some currently used medical and surgical supplies and devices would still be required for patients during their hospital stay, even after substituting SpineJack® for BKP and other surgical interventions. The applicant stated that it was unable to determine a more specific percentage for the appropriate amount of prior medical and surgical supply charges to remove from the relevant patient claims, but asserted that removing 50 percent of the charges was a conservative approach for calculation purposes. The applicant then standardized the charges and inflated the charges from FY 2018 to FY 2020. The applicant reported using an inflation factor of 11.1 percent, as published in the FY 2020 IPPS final rule (84 FR 42629).

The applicant then calculated and added the charges for the SpineJack® technology by taking the estimated per patient cost of the device, and converting it to a charge by dividing the costs by the national average CCR (cost-to-charge ratio) of 0.299 for implantable devices from the FY 2020 IPPS/LTCH PPS final rule (84 FR 42179).

In the analysis based on 100 percent of claims, the applicant computed a final inflated average case-weighted standardized charge per case of $108,760, as compared to an average case-weighted threshold amount of $77,395. In the analysis based on 77 percent of claims from only the top six MS–DRGs, the applicant computed a final inflated average case-weighted standardized charge per case of $92,904, as compared to an average case-weighted threshold amount of $72,273.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount under both analyses described previously, the applicant asserted that the technology meets the cost criterion. We are inviting public comments on whether the SpineJack® system meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that the treatment of osteoporotic vertebral compression fracture (VCF) patients with the SpineJack® system represents a substantial clinical improvement over existing technologies because clinical research supports that it reduces future interventions, hospitalizations, and physician visits through a decrease in adjacent level fractures (ALFs), which the applicant asserted are clinically significant adverse events associated with osteoporotic VCF. The applicant also asserted that treatment with the SpineJack® system greatly reduces pain scores and pain medication use when compared to BKP, which the applicant stated is the current gold standard in vertebral augmentation (VA) treatment. The applicant submitted eight studies to support that its technology represents a substantial clinical improvement over existing technologies.

The applicant explained that the SpineJack® system has been available for the treatment of patients with osteoporotic VCFs for over 10 years in Europe. The applicant explained that, as a result, the SpineJack® implant has been extensively studied, and claims from smaller studies are supported by the results from a recent, larger prospective, randomized study known as the SAKOS (SpineJack® versus Kyphoplasty in Osteoporotic Patients) study. The applicant cited the SAKOS study [347] in support of multiple clinical

[347] Noriega, D., et al., ''A prospective, international, randomized, noninferiority study comparing an implantable titanium vertebral augmentation device versus balloon kyphoplasty in the reduction of vertebral compression fractures (SAKOS study),'' *The Spine Journal,* 2019, vol. 19(11), pp. 1782–1795.

improvement claims. The applicant explained that the SAKOS study was the pivotal trial conducted in support of the FDA 510(k) clearance for the SpineJack® system and that the intent of the study was to compare the safety and effectiveness of the SpineJack® system with the KyphX Xpander Inflatable Bone Tamp (BKP) for treatment of patients with painful osteoporotic VCFs in order to establish a non-inferiority finding for use of the SpineJack® system versus balloon kyphoplasty procedure (BKP).

The SAKOS study is a prospective, international, randomized, non-inferiority study comparing a titanium implantable vertebral augmentation device (TIVAD), the SpineJack® system, versus BKP in the reduction of vertebral compression fractures with a 12-month follow-up. The primary endpoint was a 12-month responder rate based on a composite of three components: (1) Reduction in VCF fracture-related pain at 12 months from baseline by >20 mm as measured by a 100-mm Visual Analog Scale (VAS) measure, (2) maintenance or functional improvement of the Oswestry Disability Index (ODI) score at 12 months from baseline, and (3) absence of device-related adverse events or symptomatic cement extravasation requiring surgical reintervention or retreatment at the index level. If the primary composite endpoint was successful, a fourth component (absence of ALF) was added to the three primary components for further analysis. If the analysis of this additional composite endpoint was successful, then midline target height restoration at 6 and 12 months was assessed. According to the applicant, freedom from ALFs and midline VB height restoration were two additional superiority measures that were tested. According to the SAKOS study, secondary clinical outcomes included changes from baseline in back pain intensity, ODI score, EuroQol 5-domain (EQ–5D) index score (to evaluate quality of life), EQ–VAS score, ambulatory status, analgesic consumption, and length of hospital stay. Radiographic endpoints included restoration of vertebral body height (mm), and Cobb angle at each follow-up visit. Adverse events (AEs) were recorded throughout the study period. The applicant explained that researchers did not blind the treating physicians or patients, so each group was aware of the treatment allocation prior to the procedure; however, the three independent radiologists that performed the radiographic reviews were blinded to the personal data of the patients, study timepoints and results of the study.

The SAKOS study recruited patients from 13 hospitals across 5 European countries and randomized 152 patients with osteoporotic vertebral compression fractures (OVCFs) (1:1) to either SpineJack® or BKP procedures. Specifically, patients were considered eligible for inclusion if they met a number of criteria, including (1) at least 50 years of age, (2) had radiographic evidence of one or two painful VCF between T7 and L4, aged less than 3 month, due to osteoporosis, (3) fracture(s) that showed loss of height in the anterior, middle, or posterior third of the VB ≥15% but ≤40%, and (4) patient failed conservative medical therapy, defined as either having a VAS back pain score of ≥50 mm at 6 weeks after initiation of fracture care or a VAS pain score of ≥70% mm at 2 weeks after initiation of fracture care. Eleven of the originally recruited patients were subsequently excluded from surgery (9 randomized to SpineJack® and 2 to BKP). A total of 141 patients underwent surgery, and 126 patients completed the 12-month follow-up period (61 TIVAD and 65 BKP). The applicant contended that despite the SAKOS study being completed outside the U.S., results are applicable to the Medicare patient population, noting that 82 percent (116 of 141) of the patients in the SAKOS trial that received treatment (SpineJack® system or BKP) were age 65 or older. The applicant explained further that the FDA evaluated the applicability of the SAKOS clinical data to the U.S. population and FDA concluded that although the SAKOS study was performed in Europe, the final study demographics were very similar to what has been reported in the literature for U.S.-based studies of BKP. The applicant also explained that FDA determined that the data was acceptable for the SpineJack® system 510(k) clearance including two clinical superiority claims versus BKP.

The SAKOS study reported that analysis on the intent to treat population using the observed case method resulted in a 12-month responder rate of 89.8 percent and 87.3 percent, for SpineJack® and BKP respectively (p=0.0016). The additional composite endpoint analyzed in observed cases resulted in a higher responder rate for SpineJack® compared to BKP at both 6 months (88.1% vs. 60.9%; p<0.0001) and 12 months (79.7% vs. 59.3%; p<0.0001). Midline VB height restoration, tested for superiority using a *t* test with one-sided 2.5 percent alpha in the ITT population, was greater with SpineJack® than BKP at 6 months (1.14±2.61 mm vs 0.31±2.22 mm; p=0.0246) and at 12 months (1.31±2.58 mm vs. 0.10±2.23 mm; p=0.0035), with similar results in the per protocol (PP) population.

Also, according to the SAKOS study, decrease in pain intensity versus baseline was more pronounced in the SpineJack® group compared to the BKP group at 1 month (p=0.029) and 6 months (p=0.021). At 12 months, the difference in pain intensity was no longer statistically significant between the groups, and pain intensity at 5 days post-surgery was not statistically different between the groups. The SAKOS study publication also reported that at each timepoint, the percentage of patients with reduction in pain intensity >20 mm was ≥90% in the SpineJack® group and ≥80% in the BKP group, with a statistically significant difference in favor of SpineJack® at 1 month post-procedure (93.8% vs 81.4%; p=0.03). The study also reported—(1) no statistically significant difference in disability (ODI score) between groups during the follow-up period, although there was a numerically greater improvement in the SpineJack® group at most time points; (2) at each time point, the percentage of patients with maintenance or improvement in functional capacity was at or close to 100 percent; and (3) in both groups, a clear and progressive improvement in quality of life was observed throughout the 1-year follow-up period without any statistically significant between-group differences.

In the SAKOS study, both groups had similar proportions of VCFs with cement extravasation outside the treated VB (47.3% for TIVAD, 41.0% for BKP; p=0.436). No symptoms of cement leakage were reported. The SAKOS study also reported that the BKP group had a rate of adjacent fractures more than double the SpineJack® group (27.3% vs. 12.9%; p=0.043). The SAKOS study also reported that the BKP group had a rate of non-adjacent subsequent thoracic fractures nearly 3 times higher than the SpineJack® group (21.9% vs. 7.4%) (a p-value was not reported for this result). The most common AEs reported over the study period were backpain (11.8 percent with SpineJack®, 9.6 percent with BKP), new lumbar vertebral fractures (11.8 percent with SpineJack®, 12.3 percent with BKP), and new thoracic vertebral fractures (7.4 percent with SpineJack®, 21.9 percent with BKP). The most frequent SAEs were lumbar vertebral fractures (8.8 percent with SpineJack®; 6.8 percent with BKP) and thoracic vertebral fractures (5.9 percent with SpineJack®, 9.6 percent with BKP). We

also note that the length of hospital stay (in days) for osteoporotic VCF patients treated in the SAKOS trial was 3.8 ± 3.6 days for the SpineJack® group and 3.3 ±2.4 days for the BKP group (p=0.926, Wilcoxon test).

The applicant also submitted seven additional studies, which are described in more detail in this section, related to the applicant's specific assertions regarding substantial clinical improvement.

As stated previously, the applicant asserted that the SpineJack® system represents a substantial clinical improvement over existing technologies because it will reduce future interventions, hospitalizations, and physician visits through a decrease in ALFs. The applicant explained that ALFs are considered clinically significant adverse events associated with osteoporotic VCFs, citing studies by Lindsay et al.[348] and Ross et al.[349] The applicant explained that these studies reported, respectively, that having one or more VCFs (irrespective of bone density) led to a 5-fold increase in the patient's risk of developing another vertebral fracture, and the presence of two or more VCFs at baseline increased the risk of ALF by 12-fold. The applicant asserted that analysis of the additional composite endpoint in the SAKOS study demonstrated statistical superiority of the SpineJack® system over BKP (p<0.0001) for freedom from ALFs at both 6 months (88.1 percent vs. 60.9 percent) and 12 months (79.7 percent vs. 59.3 percent) post-procedure. The applicant noted that the results were similar on both the intent to treat and PP patient populations. In addition, the applicant asserted the SpineJack® system represents a substantial clinical improvement because in the SAKOS study, compared to patients treated with the SpineJack® system, BKP-treated patients had more than double the rate of ALFs (27.3 percent vs. 12.9 percent; p=0.043) and almost triple the rate of non-adjacent thoracic VCFs (21.9 percent vs. 7.4 percent).

The applicant also asserted superiority with respect to mid-vertebral body height restoration with the SpineJack® system. The applicant explained that historical treatments of osteoporotic VCFs have focused on anterior VB height restoration and kyphotic Cobb angle correction; however, research indicates that the restoration of middle VB height may be as important as Cobb angle correction in the prevention of ALFs.[350] According to the applicant, the depression of the mid-vertebral endplate leads to decreased mechanics of the spinal column by transferring the person's weight to the anterior wall of the level adjacent to the fracture, and as a result the anterior wall is the most common location for ALFs. The applicant further asserted that by restoring the entire fracture, including mid-VB height, the vertebral disc above the superior vertebral endplate is re-pressurized and transfers the load evenly, preventing ALFs.[351] The applicant stated that the SpineJack® system showed superiority over BKP with regard to midline VB height restoration at both 6 and 12 months, pointing to the SAKOS study results in the intent to treat population at 6 months (1.14±2.61 mm vs 0.31±2.22 mm; p=0.0246) and 12 months (1.31±2.58 mm vs. 0.10±2.23 mm; p=0.0035) post-procedure. The applicant noted that similar results were also observed in the PP population (134 patients in the intent-to-treat population without any major protocol deviations).

The applicant also provided two prospective studies, a retrospective study, and two cadaveric studies in support of its assertions regarding superior VB height restoration. The applicant stated that in a prospective comparative study by Noriega D., et al.,[352] VB height restoration outcomes utilizing the SpineJack® system were durable out to 3 years. This study was a safety and clinical performance pilot that randomized 30 patients with painful osteoporotic vertebral compression fractures to SpineJack® (n=15) or BKP (n=15).[353] Twenty-eight patients completed the 3-year study (14 in each group). The clinical endpoints of analgesic consumption, back pain intensity, ODI, and quality of life were recorded preoperatively and through 36-months post-surgery.[354] Spine X-rays were also taken 48 hours prior to the procedure and at 5 days, 6, 12, and 36 months post-surgery.[355] The applicant explained that over the 3-year follow-up period, VB height restoration and kyphosis correction was better compared to BKP, specifically that VB height restoration and kyphotic correction was still evident at 36 months with a greater mean correction of anterior VB height (10 ± 13% vs 2 ± 8% for BKP, p=0.007) and midline VB height (10 ± 11% vs 3 ± 7% for BKP, p=0.034), while there was a larger correction of the VB angle (−4.97° ± 5.06° vs 0.42° ± 3.43°; p=0.003) for the SpineJack® group. The applicant stated that this study shows superiority with regards to VB height restoration.

The applicant asserted that Arabmotlagh M., et al., also supported superiority with regard to VB height restoration. Arabmotlagh M., et al. reported an observational case series (with no comparison group) of SpineJack®. They enrolled 42 patients with osteoporotic vertebral compression fracture of the thoracolumbar, who were considered for kyphoplasty, 31 of whom completed the clinical and radiological evaluations up to 12 months after the procedure.[356] According to materials provided by the applicant, the purpose of the study was to evaluate the efficacy of kyphoplasty with the SpineJack® system to correct the kyphotic deformity and to analyze parameters affecting the restoration and maintenance of spinal alignment. The applicant explained that the mean VB height calculated prior to fracture was 2.8 cm (standard deviation (SD) of 0.47), which decreased to 1.5 cm (SD of 0.59) after the fracture. According to the applicant, following the procedure performed with the SpineJack® device, the VB height significantly increased to 1.9 cm (SD of 0.64; p<0.01), but was reduced to 1.8 cm (SD of 0.61; p<0.01) at 12 months post-procedure. We note that according to Arabmotlagh M., et al., these results were specifically for mean anterior VB height. The study does not appear to report results for midline VB height.[357] The applicant also stated that the mean kyphotic angle (KA) calculated prior to fracture was -1° (SD of 5.8), which

[348] Lindsay R. et al., ''Risk of new vertebral fracture in the year following a fracture,'' *Journal of the American Medical Association,* 2001, vol. 285(3), pp. 320–323.

[349] Ross P. et al., Pre-existing fractures and bone mass predict vertebral fracture incidence in women. *Annals of Internal Medicine.* 1991, vol. 114(11), pp. 919–923.

[350] Lin J et al. Better height restoration, greater kyphosis correction, and fewer refractures of cemented vertebrae by using an intravertebral reduction device: A 1-year follow-up study. *World Neurosurgery.* 2016; 90:391–396.

[351] Tzermiadianos M., et al., ''Altered disc pressure profile after an osteoporotic vertebral fracture is a risk factor for adjacent vertebral body fracture,'' *European Spine Journal,* 2008, vol. 17(11), pp. 1522–1530.

[352] Noriega D., et al., ''Long-term safety and clinical performance of kyphoplasty and SpineJack procedures in the treatment of osteoporotic vertebral compression fractures: a pilot, monocentric, investigator-initiated study,'' *Osteoporosis International,* 2019, vol. 30, pp. 637–645.

[353] Ibid.

[354] Ibid.

[355] Ibid.

[356] Arabmotlagh M., et al., ''Radiological Evaluation of Kyphoplasty With an Intravertebral Expander After Osteoporotic Vertebral Fracture,'' *Journal of Orthopaedic Research,* 2018. Doi: 10.1002.jor.24180.

[357] Arabmotlagh M., et al., ''Radiological Evaluation of Kyphoplasty With an Intravertebral Expander After Osteoporotic Vertebral Fracture,'' *Journal of Orthopaedic Research,* 2018. Doi: 10.1002.jor.24180.

increased to 13.4° (SD of 8.1) after the fracture. The applicant also stated that following the procedure performed with the SpineJack® device, KA significantly decreased to 10.8° (SD of 9.1; p<0.01); however, KA correction was lost at 12 months post-procedure with an increase to 13.3° (SD of 9.5; p<0.01).

The applicant provided a Lin et al., retrospective study of 75 patients that compared radiologic and clinical outcomes of kyphoplasty with the SpineJack® system to vertebroplasty (VP) in treating osteoporotic vertebral compression fractures to support its assertions regarding superiority with regard to midline VB height restoration.[358] The applicant stated that the radiologic outcomes from this study were: (1) The mean KA and mean KA restoration was more efficient after SpineJack® than VP at all time points (up to 1 year), except for mean KA observed postoperatively at 1 week; and (2) the mean middle VB heights and mean VB height restoration was more favorable after SpineJack® than VP.[359] We note that this study did not compare the SpineJack® system to BKP, which the applicant stated is the gold-standard in vertebral augmentation.

In the two cadaveric studies, Kruger A., et al. (2013) and Kruger A., et al. (2015), wedge compression fractures were created in human cadaveric vertebrae by a material testing machine and the axial load was increased until the height of the anterior edge of the VB was reduced by 40 percent.[360] The VBs were fixed in a clamp and loaded with 100 N in a custom made device. In Kruger A., et al. (2013), vertebral heights were measured at the anterior wall as well as in the center of the vertebral bodies in the medial sagittal plane in 36 human cadaveric vertebrae pre- and post-fracture as well as after treatment and loading in (27 vertebrae were treated with SpineJack® with different cement volumes (maximum, intermediate, and no cement), and 9 vertebrae were treated with BKP). In Kruger A., et al. (2015), anterior, central, and posterior height as well as the Beck index were measured in 24 vertebral bodies pre-fracture and post-fracture as well as after treatment (twelve treated with SpineJack® and twelve treated with BKP). The applicant asserted that Kruger A., et al. (2013) showed superiority on VB height restoration and height maintenance, and summarized that: (1) Height restoration was significantly better for the SpineJack® group compared to BKP; (2) height maintenance was dependent on the cement volume used; and (3) the group with the SpineJack® without cement nevertheless showed better results in height maintenance, yet the statistical significance could not be demonstrated.[361] The applicant asserted that Kruger A., et al. (2015) showed superiority on VB height restoration, because the height restoration was significantly better in the SpineJack® group compared with the BKP group. The applicant explained that the clinical implications include a better restoration of the sagittal balance of the spine and a reduction of the kyphotic deformity, which may relate to clinical outcome and the biological healing process.[362]

The applicant also asserted that use of the SpineJack® system represents a substantial clinical improvement with respect to pain relief. According to the applicant, pain is the first and most prominent symptom associated with osteoporotic VCFs, which drives many elderly patients to seek hospital treatment and negatively impacts on their quality of life. The applicant provided the SAKOS randomized controlled study, a prospective consecutive observational study, and a retrospective case series to support its assertions regarding pain relief with the SpineJack® system. The applicant cited the SAKOS trial for statistically significant greater pain relief achieved at 1 month and 6 months after surgery with the SpineJack® system. The applicant summarized that in the SAKOS trial (1) progressive improvement in pain relief was observed over the follow-up period in the SpineJack® system group only; (2) the decrease in pain intensity versus baseline was more pronounced in the SpineJack® system group compared to the BKP group at 1 month (p=0.029) and 6 months (p=0.021); and (3) at each time point, the percentage of patients with reduced pain intensity >20 mm was ≥90 percent in the SpineJack® system group and ≥80 percent in the BKP group, with a statistically significant difference in favor of the SpineJack® system at 1 month post-procedure (93.8% vs 81.5%; p=0.030). The applicant also noted that although continued pain score improvements were seen out to1 year for patients treated with the SpineJack® system, the difference between the treatment groups did not meet statistical significance (p=0.061). The applicant also explained that in the SAKOS study, at 5 days after surgery, there were significantly fewer patients taking central agent medications in the SpineJack® implant-treated group as compared to those in the BKP-treated group (SJ 7.4% vs. BKP 21.9%, p=0.015). According to the applicant, central analgesic agents included medications such as non-steroidal anti-inflammatory drugs (NSAIDS), salicylates, or opioid analgesics.

The applicant also cited a prospective consecutive observational study by Noriega D., et al. for statistically significant pain relief immediately after surgery and at both 6 and 12 months. Noriega D., et al. was a European multicenter, single-arm registry study that aimed to confirm the safety and clinical performance of the SpineJack® system for the treatment of vertebral compression fractures of traumatic origin (no comparison procedure).[363] The study enrolled 103 patients (median age: 61.6 years) with 108 VCFs due to trauma (n=81), or traumatic VCF with associated osteoporosis (n=22) who had a SpineJack® procedure. Twenty-three patients withdrew from the study before the 12-month visit. The study reported a significant improvement in back pain at 48 hours after SpineJack® procedure, with the mean VAS pain score decreasing from 6.6 ± 2.6 cm at baseline to 1.4±1.3 cm (mean change: −5.2±2.7 cm; p<0.001) (median relative decrease in pain intensity of 81.5 percent) for the total study population. Noriega D., et al. also reported that the improvement was maintained over the 12-month follow-up period and similar results were observed with both pure traumatic VCF and traumatic VCF in patients with osteoporosis. The traumatic VCF with osteoporosis sub-group had a mean change of −5.5 (SD=1.9) (median relative change of 81.0%) (p<0.001) at 48 hours post-surgery (n=22), and −5.7 (SD=2.3) mean change (90.3% median relative change) (p<0.001) at 12 months (n=16). The applicant stated that this study supported a claim of statistically significant pain relief immediately after surgery and at both 6 and 12 months. The applicant summarized that (1) pain

[358] Lin J., et al., ''Better Height Restoration, Greater Kyphosis Correction, and Fewer Refractures of Cemented Vertebrae by Using an Intravertebral Reduction Device: a 1-Year Follow-up Study,'' *World Neurosurg.* 2016, vol. 60, pp. 391–396.

[359] Ibid.

[360] Kruger A., et al., ''Height restoration and maintenance after treating unstable osteoporotic vertebral compression fractures by cement augmentation is dependent on the cement volume used,'' *Clinical Biomechanics,* 2013, vol. 28, pp. 725–730; and Kruger A., et al., ''Height restoration of osteoporotic vertebral compression fractures using different intervertebral reduction devices: a cadaveric study,'' *The Spine Journal,* 2015, vol. 15, pp. 1092–1098.

[361] Ibid.

[362] Ibid.

[363] Noriega D., et al., ''Clinical performance and safety of 108 SpineJack implantations: 1-year results of a prospective multicentre single arm registry study.'' *BioMed Research International.* 2015, 173872.

relief and improvements in pain scores were statistically significant immediately after treatment (48–72 hours) and at 6 and 12 months following surgery (p<0.001); and (2) the mean improvement between baseline and at 48–72 hours after the procedure (n=31) was −4.6 (2.6) (p<0.001), while the mean improvement between baseline and at the 12-month follow-up (n=22) was −6.0 (3.4) (p<0.001). We note that Noriega D., et al. did not report results for 6 months (although it does include results for 3 months versus baseline) and does not include the results of mean improvement stated by the applicant.[364] It is also unclear if the applicant intended to rely on the overall results of the study or the subgroup of traumatic VCF with osteoporosis.

The applicant also cited a retrospective case series, Renaud C., et al., for statistically significant pain relief after surgery with the SpineJack® system. Renaud C., et al., included 77 patients with a mean age of 60.9 years and 83 VCFs (51 due to trauma and 32 to osteoporosis) treated with 164 SpineJack® devices (no comparison procedure).[365] The applicant summarized that—(1) pain relief was statistically significant (p<0.001), with a pain score decrease from 7.9 pre-operatively to 1.8 at 1 month after the procedure; (2) the pain score improvement was 77 percent at hospital discharge and gradually increased to 86 percent after 1 year following surgery; and (3) the study outcomes demonstrated that the SpineJack® system provided both immediate and long-lasting pain relief.

We note that the results of the SAKOS trial do not appear to have been corroborated in any other randomized controlled study. Additionally, although the applicant stated that BKP is the gold standard in VA, there appears to be a lack of data comparing the SpineJack® system to other existing technology, such as the PEEK coiled implant (Kiva® system), particularly since the PEEK coiled system was considered the predicate device for the SpineJack 510(k). Furthermore, there appears to be a lack of data comparing the SpineJack® system to conservative medical therapy. We note there is an active study posted on *clinicaltrials.gov* comparing SpineJack® system to conservative orthopedic management consisting of brace and pain medication in acute stable traumatic vertebral fractures in subjects aged 18 to 60 years old. The clinicaltrials.gov entry indicates that findings should be forthcoming in 2020. Additionally, we note that the recent systematic reviews of the management of vertebral compression fracture (Buchbinder et al. for Cochrane (2018), Ebeling et al. (2019) for the American Society for Bone and Mineral Research (ASBMR)), do not support vertebral augmentation procedures due to lack of evidence compared to conservative medical management.[366] The ASBMR recommended more rigorous study of treatment options including ''larger sample sizes, inclusion of a placebo control and more data on serious AEs (adverse events).''

We are inviting public comment on whether the SpineJack® system meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for the SpineJack® system or at the New Technology Town Hall meeting.

m. TECENTRIQ® (Atezolizumab)

Genentech, Inc. submitted an application for new technology add-on payments for TECENTRIQ® for FY 2021. According to the applicant, TECENTRIQ® is a programmed death-ligand 1 (PD–L1) blocking antibody with four different oncology indications, including one in combination with carboplatin and etoposide, for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES–SCLC).[367] The applicant states that programmed death-ligand 1 (PD–L1) is a protein expressed on the surface of cancer and immune cells, which allows them to inactivate the T-cells of the patient's immune system that would otherwise kill them. The applicant states TECENTRIQ® blocks the PD–L1 protein, rendering the cancer cells susceptible to attack.[368] [369] TECENTRIQ® has multiple indications. The applicant has applied for the new technology add-on payment for TECENTRIQ® for its indication for ES–SCLC only.

The applicant states TECENTRIQ® was initially approved by FDA on May 18, 2016, for treatment of patients with locally advanced or metastatic urothelial carcinoma,[370] and subsequently for patients with metastatic non-small cell lung cancer (NSCLC) who have disease progression during or following platinum-containing chemotherapy on October 18, 2016; [371] for the first-line treatment of patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations on December 6, 2018; [372] and for metastatic triple negative breast cancer on March 8, 2019.[373]

TECENTRIQ® received FDA approval on March 18, 2019 in combination with carboplatin and etoposide for the first-line treatment of adult patients with ES–SCLC. The applicant states that TECENTRIQ® is the first cancer immunotherapy to be approved in the first-line treatment of ES–SCLC.[374] The applicant stated that the National Comprehensive Cancer Network (NCCN) recommends TECENTRIQ® + carboplatin + etoposide as the only category 1 preferred initial treatment for patients with ES–SCLC.[375]

[364] Ibid.

[365] Renaud C., ''Treatment of vertebral compression fractures with the cranio-caudal expandable implant SpineJack: Technical note and outcomes in 77 consecutive patients.'' *Orthopaedics & Traumatology: Surgery & Research,* 2015, vol. 101, pp. 857–859.

[366] Buchbinder R., Johnston R.V., Rischin K.J., Homik J., Jones C.A., Golmohammadi K., Kallmes D.F., ''Percutaneous vertebroplasty for osteoporotic vertebral compression fracture,'' *Cochrane Database Syst Rev.* 2018 Apr 4 and Nov 6. PMID: 29618171; Ebeling P.R., Akesson K., Bauer D.C., Buchbinder R., Eastell R., Fink H.A., Giangregorio L., Guanabens N., Kado D., Kallmes D., Katzman W., Rodriguez A., Wermers R., Wilson H.A., Bouxsein M.L., ''The Efficacy and Safety of Vertebral Augmentation: A Second ASBMR Task Force Report.'' *J Bone Miner Res.,* 2019, vol. 34(1), pp. 3–21.

[367] TECENTRIQ (atezolizumab) [prescribing information]. San Francisco, CA: Genentech, Inc., 2019.

[368] Chen, D.S., Irving, B.A., Hodi, F.S., ''Molecular Pathways: Next-Generation Immunotherapy—Inhibiting Programmed Death-Ligand 1 and Programmed Death-1,'' *Clinical Cancer Research,* 2012, 18(24), pp. 6580–6587, doi:10.1158/1078–0432.ccr–12–1362.

[369] IMFINZI® (durvalumab) [Prescribing Information]. Wilmington, DE; AstraZeneca Pharmaceuticals LP, 2019.

[370] U.S. Department of Health and Human Services. BLA Accelerated Approval. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/761034Orig1s000ltr.pdf.* Accessed August 9, 2019.

[371] U.S. Department of Health and Human Services. BLA Approval. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/761041Orig1s000ltr.pdf.* Accessed August 9, 2019.

[372] U.S. Department of Health and Human Services. Supplement Approval. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/761034Orig1s009ltr_REPLACEMENT.pdf.* Accessed August 9, 2019.

[373] U.S. Department of Health and Human Services. Accelerated Approval. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/761034Orig1s018ltr.pdf.* Accessed August 9, 2019.

[374] U.S. Department of Health and Human Services. Supplemental Approval. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/761034Orig1s019ltr.pdf.* Accessed August 9, 2019.

[375] National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology. Small Cell Lung Cancer Version 2.2019. *https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf.* Accessed August 16, 2019.

The applicant states that TECENTRIQ® is formulated into a single-dose vial for intravenous injection.[376] It further states that it is usually given in the physician office or hospital outpatient setting—as is the case for most treatments for solid tumors. The applicant explained that sometimes ES–SCLC patients are diagnosed in the inpatient setting and are treated there due to their immediate need for treatment. For subsequent doses for ES–SCLC patients, the applicant states TECENTRIQ® is generally given in the physician office or hospital outpatient setting, as it is when used in any of its other indications.

Per the applicant, lung cancer is the second most commonly diagnosed cancer and the leading cause of cancer-related death among men and women in the United States.[377] SCLC is a high-grade neuroendocrine tumor comprising small cells with minimal cytoplasm, having poorly defined cell borders, and either being absent a nucleoli or having an unremarkable nucleoli.[378] [379] The most aggressive of all lung cancers, it accounts for about 10–15 percent of lung cancer cases.[380] Key characteristics of SCLC include its rapid doubling time and the early development of widespread metastases.[381] [382] About 72 percent of SCLC cases are diagnosed at the extensive stage, which is associated with a 5-year survival rate of only 2.9 percent.[383] [384]

The applicant states that the current standard-of-care treatment for ES–SCLC is a combination of etoposide, which is FDA-approved in SCLC only in combination with cisplatin, and carboplatin, which is used in preference to cisplatin for toxicity reasons, despite being off-label.[385] Irinotecan, a topoisomerase inhibitor indicated in colon and rectum cancers only, is sometimes used in place of etoposide.[386] [387] Etoposide causes the induction of deoxyribonucleic acid (DNA) strand breaks by an interaction with DNA-topoisomerase II or the formation of free radicals, leading to cell cycle arrest (primarily at the G2 stage of the cell cycle), and cell death.[388] Carboplatin, although associated with a greater risk of myelosuppression, is often substituted for cisplatin in order to decrease the risks of emesis, neuropathy, and nephropathy.[389] Both carboplatin and cisplatin impart cytotoxicity by binding to DNA, which inhibits the process of DNA replication.[390]

According to the applicant, despite standard-of-care chemotherapy regimens using etoposide and carboplatin, the majority of patients with ES–SCLC will experience recurrence within 1 year. Median progression-free survival (PFS) and overall survival (OS) rates are 2 months and 10 months, respectively, after initial chemotherapy.[391] [392] [393]

According to the applicant, progress in the treatment of ES–SCLC has been limited. Over the past 40 years, the 2-year OS has increased from 3.4 percent to 5.6 percent, and the median OS has remained at about 10 months since the 1980s.[394] [395] [396] One paper noted that more than 40 phase III trials evaluating other regimens in SCLC have failed since 1970.[397] The applicant stated that this situation is perhaps best illustrated by reference to the National Institutes of Health's database of clinical trials. The appendix of this document presents the results of clinical trials of putative pharmacology therapies for SCLC with statuses of ''terminated'' (phase 2 and phase 3) and ''completed'' (phase 3 only).[398] [399]

The applicant asserts that there is no ICD–10–PCS code which uniquely identifies the administration of TECENTRIQ® in ES–SCLC inpatient cases. The applicant submitted a request for a unique ICD–10–PCS code for TECENTRIQ® to be effective October 1, 2020.

As stated previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and, therefore, would not be considered ''new'' for purposes of new technology add-on payments. The applicant asserts that TECENTRIQ® does not meet any of the three criteria and therefore, TECENTRIQ® is new.

[376] TECENTRIQ (atezolizumab) [prescribing information]. San Francisco, CA: Genentech, Inc., 2019.

[377] American Cancer Society. Lung Cancer Prevention and Early Detection. American Cancer Society. *https://www.cancer.org/cancer/lung-cancer/prevention-and-early-detection.html.* Accessed October 3, 2019.

[378] Meerbeeck, J.P.V., Fennell, D.A., Ruysscher, D.K.D, ''Small-cell Lung Cancer,'' *The Lancet,* 2011, 378(9804), pp.1741–1755, doi:10.1016/s0140-6736(11):60165–7.

[379] Kalemkerian, G., ''Small Cell Lung Cancer,'' *Seminars in Respiratory and Critical Care Medicine,* 2016, 37(05) pp.783–796, doi:10.1055/s-0036-1592116.

[380] WebMD, LLC. Types of Lung Cancer. *https://www.webmd.com/lung-cancer/lung-cancer-types#1.* Accessed August 15, 2019.

[381] Harris, K., Khachaturova, I., Azab, B., et al., ''Small Cell Lung Cancer Doubling Time and its Effect on Clinical Presentation: A Concise Review,'' *Sage Journals,* 2012, 6, pp.199–203, doi:10.4137/CMO.S9633.

[382] Pietanza, M.C., Averett, L., Minna, J., Rudin, C.M., ''Small Cell Lung Cancer: Will Recent Progress Lead to Improved Outcomes?,'' *Clinical Cancer Research,* 2015, (21), pp. 2244–2255, doi: 10.1158/1078-0432.CCR-14-2958.

[383] American Lung Association. Trends in Lung Cancer Morbidity and Mortality. *https://www.lung.org/assets/documents/research/lc-trend-report.pdf.* Accessed August 15, 2019.

[384] Noone, A.M., Howlader, N., Krapcho, M., et al., SEER Cancer Statistics Review, 1975–2015, based on November 2017 SEER data submission, posted to the SEER website, April 2018. Bethesda, MD: National Cancer Institute. 2018; *https://seer.cancer.gov/csr/1975_2015/results_merged/sect_15_lung_bronchus.pdf.* Accessed September 23, 2019.

[385] UpToDate, Inc. ES-Small Cell Lung Cancer: Initial Management. *https://www.uptodate.com/contents/extensive-stage-small-cell-lung-cancer-initial-management.* Accessed July 26, 2019.

[386] CAMPOSTAR (irinotecan) [prescribing information]. New York, NY: Pfizer, Inc., 2019.

[387] National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology. Small Cell Lung Cancer Version 1.2019. *https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf.* Accessed July 26, 2019.

[388] ETOPOSIDE (etoposide phosphate) [prescribing information]. Deerfield, IL: Baxter Healthcare, Corp., 2017.

[389] National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology. Small Cell Lung Cancer Version 2.2019. *https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf.* Accessed October 3, 2019.

[390] Sousa, G.F.D., Wlodarczyk, S.R., Monteiro, G., ''Carboplatin: Molecular Mechanisms of Action Associated with Chemoresistance,'' *Brazilian Journal of Pharmaceutical Sciences,* 2014, 4(50), pp. 693–701, doi:10.1590/S1984-82502014000400004.

[391] Kalemkerian, G., ''Small Cell Lung Cancer,'' *Seminars in Respiratory and Critical Care Medicine,* 2016, 37(05):783–796. doi:10.1055/s-0036-1592116.

[392] Gadgeel, S.M., Pennell, N.A., Fidler, M.J., et al., ''Phase II Study of Maintenance Pembrolizumab in Patients with ES-Small Cell Lung Cancer (SCLC),'' *Journal of Thoracic Oncology,* 2018, 13(9), pp. 1393–1399. doi:10.1016/j.jtho.2018.05.002.

[393] Rossi, A., ''Relapsed Small-Cell Lung Cancer: Platinum Re-Challenge Or Not,'' *Journal of Thoracic Disease,* 2016, 8(9), pp. 2360–2364, doi:10.21037/jtd.2016.09.28.

[394] Kalemkerian, G., ''Small Cell Lung Cancer,'' *Seminars in Respiratory and Critical Care Medicine,* 2016, 37(05), pp. 783–796, doi:10.1055/s-0036-1592116.

[395] Evans, W.K., Shepherd, F.A., Feld, R., Osoba, D., Dang, P., Deboer, G., ''VP–16 and Cisplatin as First-Line Therapy for Small-Cell Lung Cancer,'' *Journal of Clinical Oncology,* 1985, 3(11), pp. 1471–1477, doi:10.1200/jco.1985.3.11.1471.

[396] Boni, C., Cocconi, G., Bisagni, G., Ceci, G., Peracchia, G., Cisplatin and Etoposide (VP–16) as a Single Regimen for Small Cell Lung Cancer. A phase II trial,'' *Cancer,* 1989, 63(4), pp. 638–642, doi:10.1002/1097–0142(19890215)63:4>638:aid-cncr2820630406>3.0.co;2–8.

[397] Byers, L.A., Rudin, C.M., ''Small Cell Lung Cancer: Where Do We Go from Here?,'' *Cancer,* 2014, 121(5), pp. 664–672, doi:10.1002/cncr.29098.

[398] U.S. Department of Health and Human Services. Terminated Studies | Small Cell Lung Cancer Extensive Stage. *https://clinicaltrials.gov/ct2/results?cond=Small+Cell+Lung+Cancer+Extensive+Stage&Search=Apply&recrs=h&age_v=&gndr=&type=&rslt=.* Accessed August 15, 2019.

[399] U.S. Department of Health and Human Services. Completed Studies | Small Cell Lung Cancer Extensive Stage. *https://clinicaltrials.gov/ct2/results?cond=Small+Cell+Lung+Cancer+Extensive+Stage&recrs=e&age_v=&gndr=&type=&rslt=&phase=2.* Accessed August 15, 2019.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant asserts that the mechanism of action of TECENTRIQ® in ES–SCLC is not the same as or similar to an existing technology. The applicant describes TECENTRIQ® as a programmed death-ligand 1 (PD–L1) blocking antibody, and as the first and only blocking antibody to target the PD–L1/PD–1 pathway that is FDA-approved for the treatment of ES–SCLC. The applicant explains that PD–L1 is a protein expressed on the surface of cancer cells, which allows them to inactivate the T-cells of the patient's immune system which would normally attack the cancer cells. The applicant asserts that TECENTRIQ® blocks the PD–L1 protein, rendering the cancer cells susceptible to attack.[400] The applicant indicates that the current standard-of-care drugs etoposide, carboplatin, and cisplatin impart their cytotoxic effects by interfering with the processes of DNA replication.[401] [402] Therefore, the applicant states the mechanism of action of TECENTRIQ® is unique and distinct from other available forms of treatment for ES–SCLC.

With regard to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant referenced the FY 2016 IPPS/LTCH PPS Final Rule (80 FR 49445) to support that this criterion is not met in cases where the subject technology is treating a disease for which the current standard-of-care involves non-FDA-approved therapies that are also associated with different MS–DRGs. As previously noted, the applicant stated that the current standard-of-care treatment for ES–SCLC is a combination of etoposide, which is FDA-approved in SCLC only in combination with cisplatin, and carboplatin, which is used in preference to cisplatin for toxicity reasons, despite being off-label.[403] They also point out that irinotecan, a topoisomerase inhibitor indicated in colon and rectum cancers, is sometimes used in place of etoposide.[404] [405]

The applicant also stated that the MS–DRG payment system cannot differentiate between patients with NSCLC and ES–SCLC and noted that MS–DRGs 180 (Respiratory Neoplasms with MCC) and 181 (Respiratory Neoplasms with CC) are applicable to both diseases. The applicant also noted that category C34 (Malignant neoplasm of bronchus and lung) of the ICD–10–CM diagnosis coding classification system can be used to identify NSCLC and SCLC cases but does not differentiate between them. As a result, the applicant believes both TECENTRIQ® and an existing technology (such as one used to treat NSCLC) may be assigned to either of these MS–DRGs, even though, as previously noted, the NSCLC and SCLC patient populations are different.

With regard to the third substantial similarity criterion, the applicant states the use of TECENTRIQ® in ES–SCLC does not involve the treatment of the same or a similar type of disease and the same or similar patient population when compared to an existing technology.

The applicant notes this criterion was developed by CMS specifically to accommodate situations where an NTAP is sought for a new indication of a drug previously indicated for a different patient population. The applicant noted that CMS stated the following in the FY 2010 IPPS final rule (74 FR 43813): ''If, prior to the FDA approval for the new indication, the technology has not been used to treat Medicare patients for purposes consistent with the new indication, the relevant MS–DRGs may not reflect the cost of the technology. Consequently, Medicare beneficiaries may not have adequate access to the technology when used for purposes consistent with the new indication. Allowing the new technology add-on payment for the technology when used for the new indication would address this concern. For these reasons, we believe that treating an existing technology as ''new'' when approved by the FDA for a new indication may be warranted under certain circumstances.''

The applicant believes that this is the case for TECENTRIQ® and that there is no evidence of TECENTRIQ® utilization in inpatient ES–SCLC cases, in either the 2017 or 2018 Medicare Standard Analytical Files (SAF). The applicant asserts that therefore, the relevant MS–DRGs do not reflect the cost of TECENTRIQ®. Therefore, the applicant believes Medicare beneficiaries may not have adequate access to TECENTRIQ® when it is used to treat ES–SCLC patients as described previously.

Additionally, the applicant explained that although SCLC and NSCLC share a MS–DRG, they are different diseases with different patient populations, and pointed to differences between SCLC and NSCLC in terms of their staging, percentage of patients with distant stage disease at the time of diagnosis, classification, levels of PD–L1 expression, pharmacologic treatments, and 5-year relative survival rates. The applicant further explained that these diseases are not mutually exclusive; a minority of patients, 5–28 percent depending on the specimen types used, are said to have combined SCLC (C–SCLC), which is defined by the World Health Organization as SCLC combined with additional components that consist of any of the histological types of NSCLC.[406] Therefore, the applicant asserts the use of TECENTRIQ® in cases of ES–SCLC does not involve treatment of the same or a similar type of disease, in the same or a similar patient population, when compared to an existing technology, and therefore TECENTRIQ® meets the newness criterion.

We note that we received an application for new technology add-on payments for FY 2021 for IMFINZI® when used in combination with etoposide and either carboplatin or cisplatin for the first-line treatment of patients with extensive-stage small cell lung cancer (ES–SCLC). At the time of the development of this proposed rule, IMFINZI® has not yet received FDA approval for this indication. Both IMFINZI® and TECENTRIQ® seem to be intended for similar patient populations and would involve the treatment of the same conditions; patients with locally advanced or metastatic urothelial carcinoma and patients with SCLC. As noted above, we are interested in information on how these two technologies may differ from each other regarding the substantial similarity criteria and newness criterion, to inform our analysis of whether IMFINZI® and TECENTRIQ® are substantially similar to each other and therefore should be

[400] Chen, D.S., Irving, B.A., Hodi, F.S., ''Molecular Pathways: Next-Generation Immunotherapy—Inhibiting Programmed Death-Ligand 1 and Programmed Death-1,'' *Clinical Cancer Research,* 2012, 18(24), pp. 6580–6587. doi:10.1158/1078-0432.ccr-12-1362.

[401] ETOPOPHOS (etoposide phosphate) [prescribing information]. Deerfield, IL: Baxter Healthcare, Co., 2017.

[402] Sousa, G.F.D., Wlodarczyk **S.R.**, Monteiro G., ''Carboplatin: Molecular Mechanisms of Action Associated with Chemoresistance,'' *Brazilian Journal of Pharmaceutical Sciences,* 2014, 4(50), pp. 693–701, doi:10.1590/S1984-82502014000400004.

[403] UpToDate, Inc. ES-small cell lung cancer: Initial management. *https://www.uptodate.com/contents/extensive-stage-small-cell-lung-cancer-initial-management.* Accessed October 3, 2019.

[404] CAMPOSTAR (irinotecan) [prescribing information]. New York, NY: Pfizer, Inc., 2019.

[405] National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology. Small Cell Lung Cancer Version 2.2019. *https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf.* Accessed October 3, 2019.

[406] Qin, J., Lu, H., ''Combined Small-Cell Lung Carcinoma,'' *OncoTargets and Therapy,* 2018, Volume 11, pp. 3505–3511, doi:10.2147/ott.s159057.

considered as a single application for purposes of new technology add-on payments.

We are inviting public comments on whether TECENTRIQ® is substantially similar to an existing technology and whether it meets the newness criterion.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that the technology meets the cost criterion. To identify cases that may be eligible for TECENTRIQ®, the applicant searched the FY 2018 MedPAR LDS file for claims reporting an ICD–10–CM code from category C34 and considered only cases where the diagnosis codes were in the primary or admitting position to differentiate ES–SCLC from limited-stage SCLC. Cases classified with one or more of 48 surgical lung procedure codes were not considered to differentiate ES–SCLC from NSCLC. This resulted in 33,404 cases, which the applicant indicated constitute what it defines as an ES–SCLC case through the reconciliation of clinical presentation, applicable ICD–10–CM and ICD–10–PCS codes, and MedPAR data fields, which mapped to 264 MS–DRGs.

Using these 33,404 cases, the applicant then calculated the unstandardized average charges per case for each MS–DRG. The applicant determined that it did not need to remove any charges because TECENTRIQ® is administered as a combination therapy with carboplatin and etoposide to treat ES–SCLC.

The applicant then standardized the charges and inflated the charges by 1.11100 or 11.10 percent, the same inflation factor used by CMS to update the outlier threshold in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42629). The applicant then added the estimated cost of an ES–SCLC TECENTRIQ® administration to the MedPAR cases. The applicant then added the charges for TECENTRIQ® by converting the costs to a charge by dividing the cost by what the applicant described as a conservative cost-to-charge ratio of 0.5.

Based on the FY 2020 IPPS/LTCH PPS final rule correction notice data file thresholds, the average case-weighted threshold amount was $65,738. In the applicant's analysis, the final inflated average case-weighted standardized charge per case was $88,561. Because the final inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

The applicant also provided a sensitivity analysis using this same methodology but considered only the MS–DRGs representing 1 percent of case volume, producing a list of 10 MS–DRGs that cumulatively represent 88.31 percent of case volume, or 29,500 cases. Based on the FY 2020 IPPS/LTCH PPS final rule correction notice data file thresholds, the average case-weighted threshold amount was $56,987. In the applicant's analysis, the final inflated average case-weighted standardized charge per case was $88,404. Because the final inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

As noted previously, we received an application for new technology add-on payments for FY 2021 for IMFINZI®. Both IMFINZI® and TECENTRIQ® seem to be intended for similar patients. The ICD–10–CM diagnosis codes and MS–DRGs in the cost analysis for IMFINZI® differ from those used in the cost analysis for TECENTRIQ®. Specifically, as noted previously, the applicant for TECENTRIQ® searched for claims with ICD–10–CM diagnosis codes from category C34 while the applicant for IMFINZI® searched for ICD–10–CM diagnosis codes from category C34 in combination with Z51.11 or Z51.12. As noted previously, we are concerned as to why the diagnosis codes would differ between the cost analysis for IMFINZI® and for TECENTRIQ® as one analysis may lend more accuracy to the calculation depending on which is more reflective of the applicable patient population). We are inviting public comment on whether TECENTRIQ® meets the cost criterion.

With regard to substantial clinical improvement, the applicant asserts that TECENTRIQ® plus standard-of-care represents a substantial clinical improvement over existing technologies because it offers a treatment option for a patient population unresponsive to, or ineligible for currently available treatments. The applicant also believes that TECENTRIQ® represents a substantial clinical improvement because the technology demonstrates statistically significant improvement in overall survival, statistically significant improvement in progression-free survival, as well as improved HRQoL (Health-related quality of life, which is an individual's or a group's perceived physical and mental health over time) [407] and reduced symptomology.

According to the applicant, the use of TECENTRIQ® in cases of ES–SCLC was evaluated in IMpower133, a phase III (efficacy) and phase I (safety), double-blind, placebo-controlled, randomized, multicenter study designed to compare the efficacy and safety of TECENTRIQ® vs. placebo in combination with carboplatin and etoposide in patients with ES–SCLC who did not receive prior systemic therapy.[408] Over 40 percent of the population of the IMpower 133 clinical trial were of Medicare age.[409]

Key inclusion criteria were as follows: histologically or cytologically confirmed ES–SCLC as defined by the VA Lung Study Group staging system; measurable ES–SCLC according to RECIST version 1.1; ECOG PS of 0–1; no prior systemic treatment for ES–SCLC; and treated asymptomatic CNS metastases. Key exclusion criteria were as follows: history of autoimmune disease and prior treatment with CD137 agonists or immune checkpoint inhibitors.

A total of 403 patients were enrolled. Patients were stratified by gender, ECOG PS (0 or 1), and the presence of brain metastases. Baseline characteristics were comparable across both treatment arms. The following table summarizing baseline patient characteristics indicates that more than 40 percent of the patients in both treatment arms were of Medicare age.

[407] *https://www.cdc.gov/hrqol/index.htm.* Accessed December 27, 2019.

[408] Horn, .L, Mansfield, A.S., Szczęsna, A., et al., ''First-Line Atezolizumab plus Chemotherapy in Extensive Stage Small-Cell Lung Cancer,'' *New England Journal of Medicine,* 2018, 379(23), pp. 2220–2229, doi:10.1056/nejmoa1809064.

[409] Ibid.

Characteristic	TECENTRIQ® + Carboplatin + Etoposide (n=201)	Placebo + Carboplatin + Etoposide (n=202)
Median age (range), years	64 (28-90)	64 (26-87)
Age group, n (%)		
<65 years	111 (55.2)	106 (52.5)
≥65 years	90 (44.8)	96 (47.5)
Male, n (%)	129 (64.2)	132 (65.3)
ECOG PS, n (%)		
0	73 (36.3)	67 (33.2)
1	128 (63.7)	135 (66.8)
Tobacco use history, n (%)		
Current/previous smoker	74 (36.8)/118 (58.7)	74 (37.1)/124 (61.4)
Never smoker	9 (4.5)	3 (1.5)
Brain metastasis, yes, n (%)	17 (8.5)	18 (8.9)
Previous anticancer treatments, n (%)		
Chemotherapy or nonanthracycline	8 (4.0)	12 (5.9)*
Radiotherapy	25 (12.4)	28 (13.9)
Cancer-related surgery	33 (16.4)	25 (12.4)

*Limited-stage setting

At the time of data cutoff (April 24, 2018), the median follow-up was 13.9 months. The applicant states that patients treated with TECENTRIQ® + carboplatin + etoposide experienced a significantly longer OS and PFS compared with patients treated with placebo + carboplatin + etoposide in the ITT population. The 1-year OS with TECENTRIQ® + carboplatin + etoposide, compared with the placebo + carboplatin + etoposide rate, was approximately 13 percent higher; the 1-year PFS was approximately 7 percent higher, as shown in the following table that summarizes Landmark Overall Survival and Progression-free Survival Rates (Data Cutoff: April 24, 2018).

	TECENTRIQ® + Carboplatin + Etoposide (n=201)	Placebo + Carboplatin + Etoposide (n=202)
12-month OS, % (95% CI)	51.7 (44.4-59.0)	38.2 (31.2-45.3)
6-month PFS, % (95% CI)	30.9 (24.3-37.5)	22.4 (16.6-28.2)
12-month PFS, % (95% CI)	12.6 (7.9-17.4)	5.4 (2.1-8.6)

The incidence of treatment-related AEs was similar in both treatment arms. The following table provides information about the safety profiles (Data Cutoff: April 24, 2018) (safety population)—IMpower133. The most common treatment-related Grade ¾ AEs for TECENTRIQ® + carboplatin + etoposide and for placebo + carboplatin + etoposide was neutropenia (22.7 percent vs. 24.5 percent, respectively), anemia (14.1 percent vs. 12.2 percent), and decreased neutrophil count (14.1 percent vs. 16.8 percent). Treatment-related deaths occurred in three patients in the TECENTRIQ® group (due to neutropenia, pneumonia, and unspecified cause) and three patients in the placebo group (due to pneumonia, septic shock, and cardiopulmonary failure).

	TECENTRIQ® + Carboplatin + Etoposide (n=198)	Placebo + Carboplatin + Etoposide (n=196)
Treatment-related AEs, n (%)	188 (95)	181 (92)
Grades 3-4	112 (57)	110 (56)
Grade 5	3 (2)	3 (2)
SAE, n (%)	74 (37)	68 (35)
Treatment-related SAE	45 (23)	37 (19)
AEs leading to treatment withdrawal	22 (11)	6 (3)
AEs leading to withdrawal from carboplatin	5 (3)	1 (<1)
AEs leading to withdrawal from etoposide	8 (4)	2 (1)
Immune-related AEs	79 (40)	48 (25)

More patients in the TECENTRIQ® group than in the placebo group experienced immune-related AEs, with rash and hypothyroidism being the most common. The following table summarizes immune-related AEs occurring in ≥5 patients in any treatment arm (data cutoff: April 24, 2018) (safety population).

Immune-Related AEs, n (%)	TECENTRIQ® + Carboplatin + Etoposide (n=198)		Placebo + Carboplatin + Etoposide (n=196)	
	All Grades	Grades 3/4	All Grades	Grades 3/4
Rash	37 (19)	4 (2)	20 (10)	0
Hypothyroidism	25 (13)	0	1 (<1)	0
Hepatitis	14 (7)	3 (2)	9 (5)	0
Laboratory abnormalities	14 (7)	3 (2)	9 (5)	0
Infusion-related reaction	11 (6)	4 (2)	10 (5)	1 (<1)
Hyperthyroidism	11 (6)	0	5 (3)	0
Pneumonitis	4 (2)	1 (<1)	5 (3)	2 (1)

The median treatment duration of TECENTRIQ® was 4.7 months (range: 0–1), and the median number of TECENTRIQ® doses administered was 7 (range: 1–30). The median dose intensity, total cumulative dose, and median number of chemotherapy doses (four doses of carboplatin, 12 doses of etoposide) were similar in the two treatment groups.

The addition of TECENTRIQ® to carboplatin + etoposide demonstrated a statistically significant improvement in OS and PFS compared with placebo + carboplatin + etoposide for the first-line treatment of ES–SCLC. Overall, the safety profiles of TECENTRIQ® + carboplatin + etoposide and placebo + carboplatin + etoposide were comparable to the safety profiles of each individual agent; no new safety signals were identified with the combinations.

The applicant asserts that TECENTRIQ® plus standard-of-care therapy represents a substantial clinical improvement over existing technologies because it offers a treatment option for a patient population unresponsive to or ineligible for currently available treatments. The applicant also asserted that TECENTRIQ® represents a significant clinical improvement over existing technologies because the technology produces a statistically significant improvement in overall survival, a statistically significant improvement in progression-free survival, as well as improved HRQoL and reduced symptomology.

We are concerned that the survival benefit of the addition of TECENTRIQ® was a median duration of only 2 months over standard therapy and the improvement on the median progression free survival was less than one month. We are also concerned that the short survival and progression free survival may not be clinically significant. Additionally, we are concerned that the participants did not have a clinically significant improvement in their quality of life given the number of AEs in the TECENTRIQ® treatment arm combined with the number of treatments given in that arm.

We are inviting public comment on whether TECENTRIQ® meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for TECENTRIQ® or at the New Technology Town Hall meeting.

o. WavelinQ™ (4F) EndoAVF System

Becton Dickinson & Company submitted an application for new technology add-on payments for the WavelinQ™ (4F) EndoAVF System for FY 2021. According to the applicant, the predicate device, the WavelinQ™ (6F) EndoAVF System received FDA marketing authorization on June 22, 2018 for the indication of the creation

of an arteriovenous (AV) fistula using concomitant ulnar artery and ulnar vein or concomitant radial artery and radial vein in patients with minimum artery and vein diameters of 2.0 mm at the fistula creation site who have chronic kidney disease and need hemodialysis. On February 6, 2019 the FDA cleared the WavelinQ™ (4F) EndoAVF System via its 510(k) (premarket notification) pathway for an expanded access indication with a smaller 4Fr catheter. The WavelinQ 4F EndoAVF System is indicated for the creation of an AV fistula using concomitant ulnar artery and ulnar vein or concomitant radial artery and radial vein in patients with minimum artery and vein diameters of 2.0 mm at the fistula creation site who have chronic kidney disease and need hemodialysis. It is our understanding that the WavelinQ™ (4F) EndoAVF System replaces the the WavelinQ™ (6F) EndoAVF System. The applicant noted that it is applying for new technology add on payments for the WavelinQ™ (4F) EndoAVF System and not the WavelinQ™ (6F) EndoAVF System. The applicant also noted that the WavelinQ™ (4F) EndoAVF System has been cleared to treat both the radial arteries and veins and the ulnar arteries and veins. Per the applicant, the only difference between the two technologies and their respective approvals is the size of the catheters (6F vs. 4F) and the expanded indication to treat the radial arteries and veins for the WavelinQ™ (4F) EndoAVF System.

Hemodialysis, a form of treatment for kidney failure patients, is a procedure that removes wastes, salts, and fluid from a patient's blood when the kidneys can no longer perform these functions. To receive dialysis, patients require a vascular access, such as an arteriovenous (AV) fistula, to connect to the dialysis machine.

The applicant asserts that Endovascular AV fistula creation with the WavelinQ™ (4F) EndoAVF System is achieved using flexible magnetic-guided arterial and venous catheters that utilize radiofrequency energy and includes vascular embolization of the brachial vein, fistulogram, angiography (to fluoroscopically guide placement of the arterial magnetic catheter), and venography (to fluoroscopically guide placement and alignment of the venous magnetic radiofrequency [RF] catheter, ultrasound, and final fistulogram to document AV fistula creation).

The applicant asserts that the following ICD–10–CM diagnosis codes are applicable to the WavelinQ™ (4F) EndoAVF System: N18.4 (Chronic kidney disease, stage 4), N18.5 (Chronic kidney disease, stage 5) and N18.6 (End stage renal disease). The applicant also asserts that the following ICD–10–PCS procedure codes can identify the WavelinQ™ (4F) EndoAVF System: 03193ZF (Bypass right ulnar artery to lower arm vein, percutaneous approach), 031A3ZF (Bypass left ulnar artery to lower arm vein, percutaneous approach), 031B3ZF (Bypass right radial artery to lower arm vein, percutaneous approach), and 031C3ZF (Bypass left radial artery to lower arm vein, percutaneous approach).

As stated previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and, therefore, would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant asserted that the WavelinQ™ (4F) EndoAVF System uses a different mechanism of action than any commercially available technology on the market for hemodialysis fistula creation. The applicant states the WavelinQ™ (4F) EndoAVF System is not an open surgical approach, and that this is the first differentiating factor from previous methods used to create an arteriovenous fistula. The applicant also explains that WavelinQ™ (4F) EndoAVF System utilizes flexible magnetic-guided arterial and venous catheters that utilize radiofrequency energy to create a communicating channel between the arterial and venous system via an endovascular approach. Additionally, the applicant explains that as part of the procedure, the WavelinQ™ (4F) EndoAVF System also requires vascular embolization of the brachial vein, fistulogram, angiography (to fluoroscopically guide placement of the arterial magnetic catheter), and venography (to fluoroscopically guide placement and alignment of the venous magnetic RF catheter, ultrasound, and final fistulogram to document AV fistula creation). The applicant asserts that in summary, the endovascular creation of an AV fistula using radiofrequency energy delivered through magnetic-guided catheters is a unique mechanism of action.

The applicant indicates the Ellypsis® Vascular Access System (Avenu Medical) has recently been granted marketing authorization by the FDA (January 25, 2019). The applicant asserts that while Ellipsys® also supports an endovascular method of creating an AV fistula, there are several important points of differentiation between the two devices and their corresponding procedures. According to the applicant, there are different mechanisms of action, procedural processes, and anatomical locations of fistula creation as follows:

- Fistula creation; WavelinQ™ utilizes Radiofrequency ablation; Ellipsys® utilizes thermal resistance (heat).
- Embolization: WavelinQ™ requires coil embolization of the brachial vein at the time of endoAVF creation, Ellipsys® does not.
- Guidance: WavelinQ™ utilizes magnetic catheters to guide and align the location of the endoAVF creation site and Ellipsys® does not have a mechanism for aligning the fistula creation site.
- Fistula of blood vessels: WavelinQ™ offers two options for fistula creation compared to Ellipsys®:

++ First, the WavelinQ™ can create a fistula from the ulnar artery to the ulnar vein; according to the applicant, this is an unused vascular bed for traditional surgical fistula options which does not interfere with necessary blood flow for hemodialysis purposes, thus preserving all future surgical AV fistula options such as radiocephalic, brachiocephalic, and braciobasilic fistulas.

++ Second, the WavelinQ can create a fistula between the concomitant radial artery and radial vein. This method eliminates the ability to perform a future radiocephalic fistula.

++ In comparison, the Ellipsys® device is only able to create a fistula from the proximal radial artery to the perforating vein, thus eliminating any future use of a radiocephalic fistula.

- Access methods: WavelinQ™ utilizes the arterial system and venous system and Ellipsys® utilizes only the venous system.
- Imaging: there are different methods of visualization in that WavelinQ™ uses ultrasound and fluoroscopy, whereas Ellipsys® only uses ultrasound.
- Subsequent procedures: Ellipsys® requires a secondary balloon angioplasty procedure at a later date, while WavelinQ™ does not.
- Procedure Times and Complexity: eEndoAVF creation with WavelinQ™ is an 85-minute procedure, whereas endoAVF creation with Ellipsys® is a 23-minute procedure, which the applicant states represents a marked difference in procedure complexities.

With regard to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant asserted that its MS–DRG analysis showed that cases using the WavelinQ™ (4F) EndoAVF System will most often be mapped to MS–DRG 264

(Other Circulatory System O.R. Procedures), per the assignment of recently created ICD–10–PCS codes for endovascular fistula creation. The applicant anticipates that cases using the Ellipsys® Vascular Access System will also be frequently mapped to this MS–DRG as MS–DRG 264 is the most common MS–DRG for patients with surgical AV fistula creations. As such, the applicant does not see a difference in MS–DRG assignment between WavelinQ™ (4F) EndoAVF procedures and traditional surgical AV fistula creation procedures.

With regard to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology, the applicant states the WavelinQ™ (4F) EndoAVF System is indicated for the creation of an arteriovenous fistula using concomitant ulnar artery and ulnar vein or concomitant radial artery and radial vein in patients with minimum artery and vein diameters of 2.0 mm at the fistula creation site who have chronic kidney disease and need hemodialysis. The applicant further explains that the diagnoses associated with this treatment and the patient population are similar to those treated by existing procedures and technologies that are commercially available, such as surgical AV fistula creation and the Ellipsys® Vascular Access System.

As mentioned above, the WavelinQ™ (6F) EndoAVF System received FDA approval on June 22, 2018 for use in the ulnar arteries and veins. The WavelinQ™ (4F) EndoAVF System is an expanded access of the WavelinQ™ (6F) EndoAVF System and received FDA approval on February 6, 2019 for use in the radial arteries and veins as well as the ulnar arteries and veins. It seems that for purposes of use in the ulnar arteries and veins, the WavelinQ™ (4F) EndoAVF System would be considered substantially similar to the WavelinQ™ (6F) EndoAVF System as there are only minor differences (the size of the catheters) between the two devices as explained previously. As a result, we believe the newness period for the use in the ulnar arteries and veins would begin with the FDA approval of the WavelinQ™ (6F) EndoAVF System, which occurred on June 22, 2018, rather than the FDA approval of the WavelinQ™ (4F) EndoAVF System, which occurred on February 6, 2019. Finally, because the WavelinQ™ (4F) EndoAVF System received FDA approval on February 6, 2019 for use in the radial arteries and veins, it seems the newness period for the use of the device in the radial arteries and veins would begin on February 6, 2019.

As summarized previously, the manufacturer explained why it believes the WavelinQ™ (4F) EndoAVF System is not substantially similar to the Ellipsys®, specifically with regard to mechanism of action. We welcome additional comments on whether the WavelinQ™ (4F) EndoAVF System and the Ellipsys® are substantially similar to each other.

We are inviting public comments on whether the WavelinQ™ (4F) EndoAVF System is substantially similar to existing technologies and whether it meets the newness criterion.

With regard to the cost criterion, the applicant conducted the following analysis to demonstrate that the technology meets the cost criterion. The applicant searched the FY 2018 MedPAR for claims reporting an ICD–10–CM diagnosis code of N18.4, N18.5 or N18.6 to identify cases that may be eligible for the WavelinQ™ (4F) EndoAVF System. The applicant limited its analysis to the following five most common MS–DRGs that the cases mapped to, which accounted for 66 percent of all cases: MS–DRG 252 (Other Vascular Procedures with MCC), 264 (Other Circulatory System O.R. Procedures), 673 (Other Kidney and Urinary Tract Procedures with MCC), 674 (Other Kidney and Urinary Tract Procedures with CC) and 981 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC). This resulted in 2,472 cases across these five MS–DRGs.

The applicant first removed supply charges with a revenue code of 027X and also removed charges for the operating room. The applicant then standardized the charges. The applicant noted that in order to provide a conservative estimate it did not inflate the charges. The applicant then added charges for the new technology as well as procedure related charges which included operating room charges.

Based on the FY 2020 IPPS/LTCH PPS final rule correction notice data file thresholds, the average case-weighted threshold amount was $83,372. In the applicant's analysis, the final inflated average case-weighted standardized charge per case was $121,749. Because the final inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the applicant maintained that the technology meets the cost criterion.

We are inviting public comments on whether the WavelinQ™ (4F) EndoAVF System meets the cost criterion.

With regard to substantial clinical improvement, the applicant asserts that the WavelinQ™ (4F) EndoAVF System represents a substantial clinical improvement over existing technologies because it offers a treatment option for a patient population unresponsive to or ineligible for currently available treatments. The applicant also believes that WavelinQ™ (4F) EndoAVF System represents a substantial clinical improvement over existing technologies because the WavelinQ™ (4F) EndoAVF System significantly improves clinical outcomes for patients requiring hemodialysis in comparison to arteriovenous surgical fistula creation and the Ellipsys® Vascular Access System; offers higher patient satisfaction; provides a beneficial resolution to disease process treatment; and provides additional vascular access options for dialysis.

Surgical arteriovenous fistulae are the recommended type of vascular access for hemodialysis.[410] Despite initiatives to increase AVF use, fistulas are still underutilized with only 17 percent of patients initiating dialysis with an AVF and 67 percent of patients still using a central venous catheter (CVC) at 3 months after dialysis initiation.[411] Failure rates (fail to mature and become usable) for surgical AVF range from 20–60 percent.[412] [413] [414] [415] [416] AVFs also take a long time to mature—approximately 132 days.[417] Furthermore, >83 percent of AVF patients need at least one intervention in the first year,[418] typically receiving 1.5 to 3.3 additional interventions per year to mature and maintain patency.[419] [420] [421] [422] [423]

[410] National Kidney Foundation Disease Outcomes Quality Initiative (NKF–KDOQI). ''KDOQI Clinical practice guideline for vascular access, *American Journal of Kidney Diseases,* 2006, 48 (suppl 1), S176–S276.

[411] USRDS Annual Report, 2017.

[412] Asif, et al., ''Early arteriovenous fistula failure: a logical proposal for when and how to intervene,'' *Clinical Journal of American Society of Nephrology,* 2006, 1: pp. 332–339.

[413] Dember, et al., ''Effect of clopidogrel on early failure of arteriovenous fistulas for hemodialysis: a randomized controlled trial,'' *JAMA,* 2008, 299, pp. 2164–2171.

[414] Al-Jaishi, et al., ''Patency rates of the arteriovenous fistula for hemodialysis: a systematic review and meta- analysis,'' *American Journal of Kidney Diseases,* 2014, 63, pp. 464–478.

[415] USRDS Annual Report, 2017.

[416] Thamer, et al., ''Medicare costs associated with arteriovenous fistulas,'' *American Journal of Kidney Diseases,* 72(1), pp. 10- 8. Published online March 28, 2018.

[417] USRDS Annual Report, 2017.

[418] Thamer, et al., ''Medicare costs associated with arteriovenous fistulas,'' *American Journal of Kidney Diseases,* 72(1), pp. 10- 18. Published online March 28, 2018.

[419] Lee, et al., ''Tradeoffs in vascular access selection in elderly patients initiating hemodialysis

Continued

According to the applicant, in contrast, results of AVF created using the WavelinQ™ EndoAVF System have shown that endoAV fistulas have better results than surgical AVF. The applicant states that these results include higher patency with fewer post-creation interventions and higher fistula maturation as compared to the surgical AVF results reported in the literature. For example, a recent meta-analysis included four clinical studies with pooled efficacy and safety data from 157 patients using the WavelinQ™ EndoAVF System.[424] According to the applicant, the results include high procedure success of 96.8 percent and higher cannulation success than surgical AVF—82.4 percent of patients were successfully used for dialysis by 6 months. Also, the applicant asserts that the results include higher patency than surgical AVF, demonstrated by 74.8 percent primary patency (unobstruction without additional intervention) at 12 months, 79.0 percent secondary patency (unobstruction) at 12 months, and 98.12 percent functional patency (durability post-cannulation) at 12 months. The FLEX study (using the WavelinQ™ (6F) EndoAVF System) reported a procedure success rate of 97 percent and that 96 percent of endoAVFs were used for dialysis and remained patent after 6 months.[425]

The applicant indicates that a second study, the Novel Endovascular Access Trial (NEAT), which was a statistically powered, prospective, multi-center study of 60 evaluable patients and 20 roll-ins using the WavelinQ™ (6F) EndoAVF System, confirmed previous results with high procedure and cannulation success of 98 percent and 67 percent (within 12 months), respectively. Additionally, the study demonstrated a low thrombosis rate of 10.5 percent, low intervention rate of 0.46 per pt-year, and high 12-month primary and secondary patency of 69 percent and 84 percent, respectively.[426]

The applicant states that additional analyses comparing endoAVF (using the WavelinQ™ (6F) EndoAVF System) to surgical AVF showed that patients with an endoAVF had fewer secondary interventions in the first year as compared to patients with a surgical AVF, resulting in overall cost savings to payers. According to the applicant, 67 percent of endoAVF patients were free from intervention after 1 year compared to only 18 percent of surgical AVF patients.[427] [428]

The applicant also indicates a third study, the EASE study, which included 32 patients and evaluated the safety and efficacy of the WavelinQ™ (4F) EndoAVF System. The applicant states that results from EASE were consistent with previous studies, demonstrating 100 percent procedure success with a low adverse event rate, 1/32 (3.1 percent). At 6 months, 86 percent of patients were successfully cannulated for dialysis using the WavelinQ™ (4F) EndoAVF System.[429]

Additionally, the applicant noted that a fourth study, the endoAVF EU Study (using the WavelinQ™ (4F) EndoAVF System), is still enrolling. Outcomes for the first 32 patients were tabulated and included in the meta-analysis and showed consistent results to previous studies.[430]

The applicant asserts the FLEX, NEAT, EASE, and endoAVF EU Studies support that the WavelinQ™ (4F) EndoAVF System results in much lower maintenance and morbidity than the traditional surgical AVF in end-stage renal failure patients, with intervention rates for endoAVF ranging from 0.21–0.6 per pt-year and fistula maturation rates up to 86 percent at 6 months.[431] [432] [433]

The applicant also asserts the reduction in interventions with the WavelinQ™ (4F) EndoAVF System is a result of the unique procedure that minimizes vessel trauma. According to the applicant, the system creates a fistula by using radiofrequency to vaporize tissue between the artery and concomitant vein with minimal vessel trauma or manipulation of the vessels, potentially lessening the stimulus for negative remodeling that leads to frequent interventions.

The applicant states WavelinQ™ (4F) EndoAVF System offers higher patient satisfaction and beneficial resolution to disease process treatment compared to surgical AVF. According to the applicant the team Lok, C et al. was interested in patient acceptance of an endoAVF (based on the WavelinQ™ (6F) EndoAVF System) because up to 30 percent of patients refuse a surgically created AV fistula according to the reported literature.[434] [435] Therefore, the team collected data on patient satisfaction using a validated patient questionnaire to learn more about the patient experience with this new technology. The applicant asserts that results indicate patients are very satisfied with their endoAVF and would not change to another type of access.

The applicant explained some of the clinical and patient benefits of the WavelinQ™ (4F) EndoAVF System. The applicant asserts, for example, that endoAVF allows the patient to avoid open surgery, scarring, and arm disfigurement, which is important to many patients. The applicant further asserts that the endoAVF procedure improves the process of administering hemodialysis as the endoAVF matures faster compared to a surgical AVF, allowing the patient to more quickly transition away from a central venous catheter, which the applicant states has

with a catheter,'' *American Journal of Kidney Diseases,* 2018.

[420] Yang, et al., ''Comparison of post-creation procedures and costs between surgical and an endovascular approach to arteriovenous fistula creation,'' *The Journal of Vascular Access,* 2017, 18, pp. 8–14.

[421] Arnold, et al., ''Evaluation of hemodialysis arteriovenous fistula interventions and associated costs: Comparison between surgical and endovascular AV fistula,'' *Journal of Vascular and Interventional Radiology* 2018, pp. 1–9.

[422] Buickians, et al., ''The natural history of autologous fistulas as first-time dialysis access in the KDOQI era,'' *Journal of Vascular Surgery,*'' 2008, 47, pp. 415–421, discussion 20–1.

[423] Falk, et al., ''Maintenance and salvage of arteriovenous fistulas,'' *Journal of Vascular Interventional Radiology,* 2006, 17, pp. 807–813.

[424] BD WavelinQ Instructions for Use, BAW1469200 Rev. 0 02/19.

[425] Rajan, et al., ''Percutaneous creation of an arteriovenous fistula for hemodialysis access,'' *Journal of Vascular Intervenous Radiol*ogy, 2015, 26, pp. 484–490.

[426] Lok, et al., ''Endovascular proximal forearm arteriovenous fistula for hemodialysis access: Results of the prospective, multicenter novel endovascular access trial (NEAT),'' *American Journal of Kidney Diseases,* 2017, 70, pp. 486–497.

[427] Yang, et al., ''Comparison of post-creation procedures and costs between surgical and an endovascular approach to arteriovenous fistula creation,'' *The Journal of Vascular Access,* 2017, 18, pp. 8–14.

[428] Arnold, et al., ''Evaluation of hemodialysis arteriovenous fistula interventions and associated costs: Comparison between surgical and endovascular AV fistula,'' *Journal of Vascular Intervenous Radiol*ogy, 2018, pp. 1–9.

[429] Berland, et al., Endovascular Creation of an Arteriovenous Fistula with a Next Generation 4Fr Device Design for Hemodialysis Access: Clinical Experience from the EASE Study.

[430] Rajan, et al., ''Percutaneous creation of an arteriovenous fistula for hemodialysis access,'' *Journal of Vascular Intervenous Radiol*ogy, 2015, 26, pp. 484–490.

[431] Lee, et al., ''Tradeoffs in vascular access selection in elderly patients initiating hemodialysis with a catheter,'' *American Journal of Kidney Diseases,* 2018.

[432] Harms, et al., ''Outcomes of arteriovenous fistulas and grafts with or without intervention prior to successful use,'' *Journal of Vascular Surgery,*'' 2016, 64(1), pp. 155–162.

[433] Berland et al., Endovascular Creation of an Arteriovenous Fistula with a Next Generation 4Fr Device Design for Hemodialysis Access: Clinical Experience from the EASE Study.

[434] Lok, C. et al., ''Patient perceptions of a new non-surgical approach to arteriovenous fistula creation and use for hemodialysis,'' *Nephrology Dialysis Transplantation,* 2017, 32 (Supplement 3) iii329–iii343.

[435] Casey, et al., ''Patients' perspectives on hemodialysis vascular access: A systematic review of qualitative studies,'' *American Journal of Kidney Diseases,* 2014, vol. 64, pp. 937–953.

a high rate of complication including infection. In addition, the applicant states that WavelinQ™ (4F) EndoAVF requires less follow-on maintenance such that patients are not in and out of the hospital for additional interventions to maintain the primary patency of the fistula.[436] [437] The applicant states that this has the potential to increase patient acceptance of an AVF as surgical fatigue is cited as the primary reason patients elect a permanent CVC over a surgical AVF.[438] The applicant also suggests the WavelinQ™ (4F) EndoAVF System provides additional vascular access options for dialysis in comparison to surgical AVF and the Ellipsys® Vascular Access System.[439] [440]

The applicant asserts the WavelinQ™ (4F) EndoAVF System creates additional options for establishing arteriovenous access, that is another anatomic site for creating a fistula that neither traditional surgical AVFs nor the Ellipsys® Vascular Access System can offer. According to the applicant, patients are given an extra location in the mid-arm for a fistula because the WavelinQ™ (4F) EndoAVF System uses vessels deep in the arm that are not used in surgical fistula creation and are only accessible endovascularly via the unique mechanism of WavelinQ™ consisting of action using magnetically guided arterial and venous catheters. The applicant suggests this additional access creation site extends the potential time a patient can undergo dialysis with an autogenous fistula before exhausting vessels and requiring an AV graft or CVC.

The applicant asserts the WavelinQ™ (4F) EndoAVF System is indicated for the creation of an arteriovenous fistula using concomitant ulnar artery and ulnar vein or concomitant radial artery and radial vein in patients with minimum artery and vein diameters of 2.0 mm at the fistula creation site who have chronic kidney disease and need hemodialysis. According to the applicant, the ulnar artery to ulnar vein fistula is unique to the WavelinQ™ (4F) EndoAVF System in comparison to both traditional surgical fistula creation and the Ellipsys® Vascular Access System. The applicant states that it enables the preservation of all future surgical AVF options such as a radiocephalic, brachiocephalic and brachiobasilic fistula as it utilizes an entirely different vascular bed for both arterial and venous blood flow.

With regard to the information previously summarized, we are concerned that there is no study directly comparing WavelinQ™ (4F) Endo AVF System to surgical AVF or Ellipsys® Vascular Access System; rather, the studies provided compare historical data for surgical AVF to data on the results of AVF created using both the WavelinQ™ Endo AVF (6F) and (4F) systems. We are also concerned as to whether the data demonstrates if the WavelinQ™ (4F) EndoAVF System significantly improves clinical outcomes for patients requiring hemodialysis in comparison to surgical AVF and the Ellipsys® Vascular Access System due to the limited number of participants in the clinical trials, and whether the results are generalizable to the entire Medicare population due to the limited number of participants.

We are inviting public comments on whether the WavelinQ™ (4F) EndoAVF System meets the substantial clinical improvement criterion.

We received a written public comment from the applicant in response to the New Technology Add-on Payment Town Hall meeting regarding the application of WavelinQ™ (4F) EndoAVF System for new technology add-on payments.

Comment: The applicant addressed a question posed at the town hall meeting regarding how the WavelinQ™ (4F) EndoAVF System is different from the Ellipsys® Vascular Access System. The applicant stated that the WavelinQ™ utilizes a different method for fistula creation, radiofrequency ablation, whereas the Ellipsys® utilizes thermal resistance (heat). The applicant further stated that the WavelinQ™ requires coil embolization of the brachial vein at the time of endoAVF creation while the Ellipsys® does not. The applicant stated that the WavelinQ™ utilizes magnetic catheters to guide and align the location of the endoAVF creation site, and that the Ellipsys® does not have a mechanism for aligning the fistula creation site. The applicant stated that the WavelinQ™ offers two options for fistula creation. The applicant stated that the WavelinQ™ (4F) EndoAVF can create a fistula from the ulnar artery to the ulnar vein. According to the applicant this is an unused vascular bed for traditional surgical fistula options which does not interfere with necessary blood flow for hemodialysis purposes, thus preserving all future surgical AV fistula options such as radiocephalic, brachiocephalic and braciobasilic fistulas. Second, it can create a fistula between the concomitant radial artery and radial vein. Per the applicant, this method of fistula creation eliminates the ability to perform a future radiocephalic fistula as an option in the future.

The applicant further stated that in comparison, Ellipsys® is only able to create a fistula from the proximal radial artery to the perforating vein, thus eliminating any future use of a radiocephalic fistula. The applicant asserts that the access methods are different—WavelinQ™ utilizes the arterial system and venous system and that the Ellipsys® utilizes only the venous system. The applicant asserts that the methods of visualization are also different. The WavelinQ™ uses ultrasound and fluoroscopy, whereas the Ellipsys® only uses ultrasound. With regard to subsequent procedures, Ellipsys® requires a secondary balloon angioplasty procedure at a later date, while WavelinQ™ does not. The applicant asserts that procedure times and complexity are also different—endoAVF creation with WavelinQ™ is an ~85-minute procedure, whereas endoAVF creation with Ellipsys® is a ~23-minute procedure, which the applicant states represents a marked difference in procedure complexities.

The applicant also addressed a question regarding available randomized, controlled studies comparing the WavelinQ™ (4F) EndoAVF System to surgical AVFs. The applicant stated that as mentioned during the Town Hall, while there are no current head to head RCTs comparing the two fistula types, there are two published retrospective studies that utilize a Propensity Score Matching Analysis to compare WavelinQ™ data from the NEAT study with two separate data sources for AVF patients.

The applicant stated that the first study was conducted by Yang, et al. and was published in the Journal of Vascular Access in 2017. This study compared AVF post-creation procedures and their associated costs for patients with surgical AV fistulas to patients with fistulas created using WavelinQ™. A random 5 percent sample from Medicare's Standard Analytic Files was extracted and used in comparison to patients from the NEAT study. Patients were matched 1:1 using propensity score matching of baseline demographic and clinical characteristics. Patient follow up data from inpatient, outpatient, and physician claims were

[436] Yang, et al., ''Comparison of post-creation procedures and costs between surgical and an endovascular approach to arteriovenous fistula creation,'' *The Journal of Vascular Access,* 2017, 18, pp. 8–14.

[437] Arnold, et al., ''Evaluation of hemodialysis arteriovenous fistula interventions and associated costs: Comparison between surgical and endovascular AV fistula,'' *Journal of Vascular Intervenous Radiol*ogy, 2018, pp. 1–9.

[438] Chaudhry, et al., ''Seeing eye to eye: The key to reducing catheter use,'' *The Journal of Vascular Access,* 2011, 12, pp. 120–126.

[439] BD WavelinQ Instructions for Use, BAW1469200 Rev. 0 02/19.

[440] Avenue Medical Ellypsis Instructions for Use, LB015–002 Rev B, Released 11/2018.

used to identify post-creation procedures and to estimate average procedure costs. Of 3764 Medicare surgical AVF patients, 60 successfully matched 1:1 with patients from the NEAT study. Key results were as follows:

- Post-creation procedural event rate was 3.43 per patient year and 0.59 per patient year ($p<0.05$) for surgical and WavelinQ™ fistulas, respectively.
- Average first year post-AVF creation costs per patient-year for patients who received a WavelinQ™ fistula were $11,240 USD lower than costs for a surgical fistula.

The second study was conducted by Arnold, et al. and was published in the Journal of Vascular Interventional Radiology in 2018. This study compared the rate of AVF interventions in both incident and prevalent end-stage kidney disease patients, their associated costs and intervention-free survival between patients with surgically created AVFs vs. patients with an endoAVF created using WavelinQ™. Data from the USRDS was abstracted and matched 1:1 with patients from the NEAT study using propensity score matching. Post fistula creation event rates, intervention-free survival, and costs were compared between patients with surgically created fistulas and patients with a WavelinQ™ fistula. The applicant stated that key results were as follows:

- In incident patients, post-creation event rates were 7.22 per patient year and 0.74 per patient year ($p<0.0001$) for surgical and WavelinQ™ fistulas, respectively.
- In prevalent patients, post-creation event rates were 4.10 per patient year and 0.46 per patient year ($p<0.0001$) for surgical and WavelinQ™ fistulas, respectively.
- Expenditures for post-creation interventions were $16,494 and $13,389 less in incident and prevalent patients with a WavelinQ™ fistula, respectively.

The applicant also provided written comments addressing the availability of data from the EU post market study. The applicant stated that while there are no plans at this time to publish the EU post market study in a medical journal, the data have been made available to the public via WavelinQ's Instructions for Use (IFU). The applicant also provided a PDF copy of the most recent IFU which contained a summary of the study safety and effectiveness measures.

Response: We appreciate the applicant's comments. We will take these comments into consideration when deciding whether to approve new technology add-on payments for WavelinQ™.

o. Zulresso™

Sage Therapeutics submitted an application for new technology add-on payments for ZULRESSO™ for FY 2021. ZULRESSO™ (brexanalone) is a neuroactive steroid gamma-aminobutyric acid $(GABA)_A$ receptor positive modulator indicated for the treatment of postpartum depression (PPD) in adults administered via a continuous intravenous infusion.

According to the applicant, PPD is a major depressive episode that occurs following delivery, though onset of symptoms may occur during pregnancy. Per the applicant, mothers with PPD may present with a variety of symptoms, which must be present most of the time for 2 weeks or more in order for PPD to be diagnosed. These depressive symptoms may persist throughout and beyond the first postnatal year if PPD is left untreated. As described by the applicant, these symptoms may include trouble bonding with, and doubt in ability to care for, their baby; thoughts of self-harm or harm to baby; feelings of worry, anxiety, sadness, moodiness, irritability, and/or restlessness; crying more often or without apparent reason; experiencing anger or rage; sleep disturbances; changes in appetite; difficulty concentrating; and withdrawal from friends and family. According to the applicant, PPD may affect the mother's ability to function with potential considerable risks such as self-harm, and PPD may also be associated with suicidal ideation.

The applicant stated that PPD is one of the most common complications during and after pregnancy, affecting more than 400,000 women in the United States. The applicant noted that women diagnosed with PPD who are disabled may be otherwise eligible for Medicare, and some may be eligible for Medicaid as well. While the studies summarized did not specifically target Medicare patients, the applicant believes that these results can be generalized to Medicare patients diagnosed with PPD.

The applicant stated that the precise cause of PPD is unknown, though there are multiple hypotheses about the mechanism of disease of PPD. The applicant reported that levels of allopregnanolone, the predominant metabolite of progesterone, increase during pregnancy and decrease substantially after childbirth. Per the applicant, preclinical evidence indicated that rapid changes in levels of allopregnanolone confer dramatic behavioral changes and may trigger PPD in some women.[441]

As reported in a study submitted by the applicant, the GABAergic deficit hypothesis of depression states that a deficit of GABAergic transmission in defined neural circuits is causal for depression. According to the study, conversely, an enhancement of GABA transmission, including that triggered by selective serotonin reuptake inhibitors or ketamine, has antidepressant effects. The study reported that ZULRESSO™, an intravenous formulation of the endogenous neurosteroid allopregnanolone, showed clinically significant antidepressant activity in postpartum depression. According to the study, by allosterically enhancing $GABA_A$ receptor function, the antidepressant activity of allopregnanolone is attributed to an increase in GABAergic inhibition. In addition, allopregnanolone may stabilize normal mood by decreasing the activity of stress-responsive dentate granule cells and thereby sustain resilience behavior. The researchers concluded that therefore, allopregnanolone may augment and extend its antidepressant activity by fostering resilience.[442]

The applicant stated that prior to FDA approval of ZULRESSO™, there were no medicines specifically indicated for PPD. The applicant indicated that the regimens historically employed for the treatment of patients who have been diagnosed with PPD have generally consisted of medications typically used for major depression or other mood disorders. As described by the applicant, these pharmacological therapies include—

- Selective serotonin reuptake inhibitors (SSRIs), such as sertraline, fluoxetine, and paroxetine, which selectively block the reuptake of serotonin;
- Serotonin and norepinephrine reuptake inhibitors (SNRIs) such as venlafaxine, duloxetine, and milnacipran, which selectively block the reuptake of serotonin and norepinephrine;
- Monoamine oxidase inhibitors (MAOIs) such as phenelzine, which cause an accumulation of amine neurotransmitters and are not commonly used, owing to the adverse reactions with concomitant medications and various food groups; and

[441] Kanes, SJ, Colquhoun, H, Doherty, J, Raines, S, Hoffmann, E, Rubinow, DR, Meltzer-Brody, S. ''Open-label, proof-of-concept study of brexanolone in the treatment of severe postpartum depression,'' *Human Psychopharmacology: Clinical & Experimental,* 2017, Vol. 32(2).

[442] Lüscher, B, Möhler, H, ''Brexanolone, a neurosteroid antidepressant, vindicates the GABAergic deficit hypothesis of depression and may foster resilience,'' *F1000Research,* 2019, vol. 751.

• Tricyclic antidepressants (TCAs), like nortriptyline, which are antimuscarinic drugs that block the reuptake of both serotonin and norepinephrine and have variable sedative properties.

The applicant indicated that non-pharmacological treatments, such as psychotherapies, including cognitive behavioral therapy, psychosocial community-based intervention, and dynamic therapy have also been used to treat PPD.

Based on market research conducted by the applicant, the applicant asserted that current treatment options for patients who have been diagnosed with PPD present potential challenges for patients such as: Long wait times for an appointment and difficulties scheduling follow-up appointments with providers; insurance coverage challenges; delays or interruptions in treatment; changes in medications or doses (which may or may not be effective): And the lengths of the treatment plan being longer than expected.

With respect to the newness criterion, the FDA granted ZULRESSO™ Priority Review and Breakthrough Therapy designations, and on March 19, 2019, approved ZULRESSO™ for the treatment of PPD in adult women. On June 17, 2019, the Drug Enforcement Administration (DEA) placed ZULRESSO™ into Schedule IV of the Controlled Substances Act (84 FR 27938 through 27943), after which it became commercially available. Currently, there are no ICD–10–PCS procedure codes to uniquely identify procedures involving ZULRESSO™. We note that the applicant has submitted a request for approval for two unique ICD–10–PCS codes for the administration of ZULRESSO™ beginning in FY 2021.

As discussed previously, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, according to the applicant, ZULRESSO™ does not use the same or a similar mechanism of action when compared to existing treatments. The applicant indicated that prior to the approval of ZULRESSO™, certain antidepressants were prescribed for the treatment of PPD; however, these antidepressants are not specifically indicated for PPD. In addition, the applicant asserted that ZULRESSO™ does not use the same or a similar mechanism of action as current antidepressants, including SSRIs, SNRIs, MAOIs, and TCAs. The applicant stated that ZULRESSO™ works differently because it does not directly affect monoaminergic systems, with the mechanism of action believed to be related to ZULRESSO's™ positive allosteric modulation of $GABA_A$ receptors. Therefore, the applicant asserted that ZULRESSO™ utilizes a different mechanism of action than currently available treatment options.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant stated that the antidepressants and non-pharmacological treatments historically used to treat PPD are traditionally used in the outpatient setting; however, patients with more severe symptoms of PPD who are hospitalized would likely have the same diagnosis (F53.0—Postpartum depression) and be assigned to the same MS–DRG as ZULRESSO™ patients, MS–DRG 881 (Depressive Neuroses).

With respect to the third criterion, whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population, according to the applicant, the use of ZULRESSO™ for treating PPD would involve treatment of a similar patient population as compared to other therapies historically used to treat PPD. However, the applicant noted that there are no other treatments or technologies that are specifically indicated for the treatment of PPD.

As summarized previously, the applicant maintains that ZULRESSO™ meets the newness criterion and is not substantially similar to existing technologies because it has a unique mechanism of action for treating PPD and is the only therapy specifically indicated for the treatment of PPD. We are inviting public comments on whether ZULRESSO™ is substantially similar to any existing technologies and whether ZULRESSO™ meets the newness criterion.

With regard to the cost criterion, the applicant used the FY 2018 MedPAR Hospital Limited Data Set (LDS) to determine the MS–DRGs to which cases representing potential patient hospitalizations that may be eligible for treatment involving ZULRESSO™ may be assigned. The applicant identified these potential cases as those with a principal or secondary diagnosis code of F53 (Puerperal psychosis), excluding MA cases and claims submitted only for GME payment. The applicant noted that ICD–10–CM code F53.0 (Postpartum depression) became effective October 1, 2018, and was not found on any FY 2018 inpatient claims. The applicant identified 76 cases reporting ICD–10–CM diagnosis code F53 spanning 26 different MS–DRGs, with approximately 58 percent of these potential cases mapping to the following 3 MS–DRGs, out of which approximately 49 percent of those potential cases mapped to the top 2 MS–DRGs:

MS-DRG	MS-DRG Title
MS-DRG 776	Postpartum and Post Abortion Diagnoses without O.R. Procedure
MS-DRG 807	Vaginal Delivery without Sterilization/D&C without CC/MCC
MS-DRG 885	Psychoses

The applicant did not remove charges for the prior technology or the technology being replaced because the historical treatment regimens, such as oral anti-depressants, do not need to be stopped during treatment with ZULRESSO™. The applicant also noted that ZULRESSO™ is the first and only FDA-approved treatment specifically indicated for PPD so there are no prior technology charges to remove. The applicant then standardized the FY 2018 charges using the FY 2018 impact file and inflated the charges to FY 2020 using the 2-year inflation factor of 11.1 percent (1.11100) published in the FY 2020 IPPS/LTCH PPS final rule (see 84 FR 42629). The applicant then added charges for ZULRESSO™, based on the average per discharge cost of ZULRESSO™ inflated by the inverse of the national average CCR for pharmacy costs of 0.189. The applicant calculated a final average case-weighted standardized charge per case of $225,056. Based on the FY 2020 IPPS/LTCH PPS final rule correction notice

data file thresholds, the applicant calculated an average case-weighted threshold amount of $33,012. The applicant stated that ZULRESSO™ exceeded the average-case-weighted threshold amount and, therefore, meets the cost criterion.

As noted previously, the 76 cases reporting ICD–10–CM diagnosis code F53 span 26 different MS–DRGs, with very few observations in most of these MS–DRGs. We note that a sub-analysis of the top 2 MS–DRGs—which represent 49 percent of the cases—would still exceed the threshold. We also note that a sub-analysis assigning 100 percent of the cases to the highest paying of these 26 MS–DRGs would also still exceed the threshold.

We are concerned with the limited number of cases in the sample the applicant analyzed. However, we acknowledge the difficulty in obtaining cost data for a condition that has low prevalence in the Medicare population. We are inviting public comments on whether ZULRESSO™ meets the cost criterion.

With regard to substantial clinical improvement, the applicant asserted that, because there is no other treatment option specifically approved by the FDA to treat PPD, ZULRESSO™ represents a substantial clinical improvement over existing technologies. In support of this statement, the applicant submitted the FDA approval letter and news release indicating that the approval of ZULRESSO™ marks the first time a drug has been specifically approved to treat PPD.[443] The applicant also asserted that ZULRESSO™ represents a substantial clinical improvement because the technology significantly reduces depressive symptoms and improves patients' functioning. The applicant submitted three studies to support its assertion that ZULRESSO™ represents a substantial clinical improvement over existing technologies by improving depressive symptoms and patients' functioning.

The first study submitted (202A) was a Phase II, multicenter, randomized, double-blind, parallel-group, placebo-controlled clinical trial with 30-day follow-up in women diagnosed with severe PPD. Patients with severe PPD (n=21) were randomized to receive a single, continuous infusion of ZULRESSO™ or placebo for 60 hours. The primary endpoint was the change from baseline in the 17-item Hamilton Depression Rating Scale (HAM–D) total score at the end of the 60-hour treatment period, compared to placebo. At the end of the 60-hour infusion, the least-squared (LS) mean reduction in HAM–D total score from baseline was 21.0 points in the ZULRESSO™ group compared with 8.8 points in the placebo group. The researchers concluded that in women with severe PPD, infusion of ZULRESSO™ resulted in a significant and clinically meaningful reduction in HAM–D total score, compared with placebo.[444]

The second and third studies submitted (202B and 202C) were Phase III, multicenter, randomized, double-blind, parallel-group, placebo-controlled clinical trials with 30 day follow-up conducted at 30 clinical research centers and specialized psychiatric units in the United States. The studies included women between the ages of 18–45 years, 6 months postpartum or less at screening, with PPD and a qualifying score on the HAM–D. In both studies, patients were randomly assigned to receive a single, continuous 60-hour infusion of ZULRESSO™ or matching placebo. The primary endpoint in both studies was the change from baseline in the 17-item HAM–D total score at 60 hours, compared with placebo. Study 202B consisted of patients who were diagnosed with severe PPD (HAM–D score ≥26) who were randomly assigned to receive a single intravenous injection of either ZULRESSO™ 90 μg/kg per h (BRX90), ZULRESSO™ 60 μg/kg per hour (BRX60), or matching placebo for 60 hours. Study 202C consisted of patients who were diagnosed with moderate PPD (HAM–D score of 20 to 25) who were randomly assigned to BRX90 or matching placebo for 60 hours. Three hundred and seventy-five women were simultaneously screened across both studies, of whom 138 were randomly assigned to receive either BRX90 (n=45), BRX60 (n=47), or placebo (n=46) in Study 202B, and 108 were randomly assigned to receive BRX90 (n=54) or placebo (n=54) in Study 202C. In study 202B, at hour 60, the LS mean reduction in HAM–D total score from baseline was 19.5 points in the BRX60 group and 17.7 points in the BRX90 group, compared with 14.0 points in the placebo group. In Study 202C, at hour 60, the LS mean reduction in HAM–D total score from baseline was 14.6 points in the BRX90 group compared with 12.1 points for the placebo group. The researchers concluded that administration of ZULRESSO™ injection for PPD resulted in significant and clinically meaningful reductions in HAM–D total score at hour 60 compared with placebo, with rapid onset of action and durable treatment response during the study period of 30 days.[445]

The applicant provided data from the clinical studies cited previously to support that ZULRESSO™ improves patients' depressive symptoms as measured by a reduction in the HAM–D score at hour 60, and sustained at day 30. The applicant cited data from the Phase II study (202A) that, at the end of the 60 hour infusion, the LS mean reduction in HAM–D total score was significantly larger for the ZULRESSO™ (90 μg/kg/h) group compared with the placebo group (21.0 vs 8.8 points, respectively). Prespecified secondary analyses showed a mean difference of −11.3 points between groups as early as 24 hours after infusion, with significant improvements also seen for the ZULRESSO™ group at 36, 48, 60, and 72 hours, as well as days 7 and 30. A greater percentage of patients in the ZULRESSO™ group achieved a treatment response (defined as ≥50% reduction from baseline in HAM–D total score) compared to the placebo group, with a significant difference observed at hour 72 (80% vs. 27%) and day 7 (80% vs. 20%). At hour 60, 70 percent of patients in the ZULRESSO™ group and 36 percent of patients in the placebo group had a treatment response. A greater percentage of patients treated with ZULRESSO™ achieved remission (HAM–D total score ≤7) at hour 60 compared with the placebo group (70.0% vs. 9.1%). The difference was significant at hours 24, 48, 60, and 72, and days 7 and 30.[446]

The applicant cited data from the Phase III multicenter study of patients with severe PPD (202B) that at hour 60, and sustained at day 30, the LS mean reduction in HAM–D total score was significantly greater for the ZULRESSO™ groups, compared to the

[443] Food and Drug Administration, ''FDA approves first treatment for post-partum depression,'' *https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-post-partum-depression.*

[444] Kanes, S., Colquhoun, H., Gunduz-Bruce, H., Raines, S., Arnold, R., Schacterle, A., Doherty, J., Epperson, C.N., Deligiannidis, K.M., Riesenberg, R., Hoffmann, E., Rubinow, D., Jonas, J., Paul, S., Meltzer-Brody, S., ''Brexanolone (SAGE–547 injection) in post-partum depression: a randomised controlled trial.'' *The Lancet.* 2017,vol. 390(10093), pp. 480–489.

[445] Meltzer-Brody, S., Colquhoun, H., Riesenberg, R., Epperson, C.N., Deligiannidis, K.M., Rubinow, D.R., Li, H., Sankoh, A.J., Clemson, C., Schacterle A., Jonas, J., Kanes, S., ''Brexanolone injection in post-partum depression: two multicentre, double-blind, randomised, placebo-controlled, phase 3 trials,'' *The Lancet,* 2018, vol. 392(10152), pp. 1058–1070.

[446] Kanes, S., Colquhoun, H., Gunduz-Bruce, H., Raines, S., Arnold, R., Schacterle, A., Doherty, J., Epperson, C.N., Deligiannidis, K.M., Riesenberg, R., Hoffmann, E., Rubinow, D., Jonas, J., Paul, S., Meltzer-Brody, S., ''Brexanolone (SAGE–547 injection) in post-partum depression: a randomised controlled trial.'' *The Lancet,* 2017, vol. 390(10093), pp. 480–489.

placebo groups. At hour 60, the LS mean reduction in HAM–D total score was 17.7 points in the BRX90 group and 19.5 points in the BRX60 group, compared to 14.0 points in the placebo group. At all-time points from hour 24 to day 30, the percentage of patients achieving HAM–D response (≥50% reduction from baseline in HAM–D total score) was higher in both ZULRESSO™ groups compared with placebo, with statistical significance achieved for both ZULRESSO™ groups across multiple timepoints compared with placebo. The percentage of patients achieving HAM–D remission (total score ≤7) was numerically higher in both ZULRESSO™ groups between 24 and 72 hours and at day 30 compared with the placebo group.[447]

The applicant cited data from the Phase III multicenter study of patients with moderate PPD (202C) that at the end of the 60 hour infusion, the LS mean reduction in HAM–D total score was significantly greater in the ZULRESSO™ BRX90 group compared with the placebo group (14.6 vs 12.1, respectively). At all time points from hour 8 through day 14, the percentage of patients achieving HAM–D remission (total score ≤7) was numerically higher for the ZULRESSO™ BRX90 group compared with the placebo group, with statistical significance achieved at multiple time points, including at the end of the 60 hour infusion.[448]

The applicant cited pooled data from the ZULRESSO™ BRX90 groups in the Phase II (202A) and Phase III (202B and 202C) studies showing a significant LS mean reduction in HAM–D total score compared with the placebo group at hour 60 (17.0 vs 12.8 points). Similar to the individual studies, the integrated BRX90 analysis showed a rapid decrease in HAM–D scores (that is, depressive symptoms) in the BRX90 group compared with the placebo groups, which was sustained until day 30. At the end of the 60 hour infusion, the LS mean reduction in HAM–D total score from baseline was significantly larger in the BRX90 group than the placebo group (LS mean difference −4.1), which was also observed at 24 hours (LS mean difference −3.0) and was sustained at day 30 (LS mean difference −2.6).[449]

The applicant provided data from the clinical studies cited previously to support that ZULRESSO™ improves patients' functioning scores, as measured by the Clinical Global Impressions Scale-Improvement (CGI–I). The applicant cited data from the Phase II study (202A) that the observed improvement in symptoms of postpartum depression following ZULRESSO™ administration was evidenced by the significant treatment difference observed for CGI–I response. At day 30, 3 (27.3%) patients in the placebo group vs. 8 (80.0%) patients treated with ZULRESSO™ were considered CGI–I responders with a score of ''1—very much improved'' or ''2—much improved.''[450]

The applicant cited data from the Phase III study of patients with severe PPD (202B) that patients' functioning scores, as measured by CGI–I, improved at hour 60, and sustained at day 30. The proportion of patients who achieved a CGI–I response (score of ''1—very much improved,'' or ''2—much improved'') at 60 hours was significantly higher in both ZULRESSO™ groups. The proportion of BRX90 patients who achieved a CGI–I response was also significantly higher than the placebo group at hour 72 and day 30 and significantly higher in the BRX60 group compared to placebo at timepoints from hours 36 to 72 and days 7 and 30.[451]

The applicant cited data from the Phase III study of patients with moderate PPD (202C) that the proportion of patients who achieved a CGI–I response was significantly higher for the BRX90 group compared with the placebo group at hour 60. These significant increases in CGI–I response occurred as early as 36 hours and were sustained at day 7.[452]

The applicant provided data from the clinical studies cited previously to support that ZULRESSO™ improves patients' depressive symptoms, as measured by the Montgomery-Asberg Depression Rating Scale (MADRS). The applicant cited data from the Phase II study (202A) that ZULRESSO™ improved patients' depressive symptoms, as measured by the MADRS, at hour 60 and sustained at day 30. Through the study period, patients in the ZULRESSO™ (90 μg/kg/h) group showed significant differences in MADRS score compared with the placebo group (hour 24, P=0.004; hour 60, P=0.01; day 30, P=0.01).[453]

The applicant cited data from the Phase III study of patients with severe PPD (202B) that ZULRESSO™ improved patients' depressive symptoms, as measured by the MADRS, at hour 60. Numerically greater improvement from baseline in MADRS total score was observed for both ZULRESSO™ (60 μg/kg/h and 90 μg/kg/h) treatment groups compared with the placebo group at hour 60 and day 30. This difference was statistically significant at hour 60 for ZULRESSO 60 μg/kg/h (LS mean difference vs placebo, −6.9).[454]

The applicant cited data from the Phase III study of patients with moderate PPD (202C) that ZULRESSO™ improved patients' depressive symptoms, as measured by the MADRS, at hour 60. There was a statistically significant improvement from baseline in the MADRS total score for the ZULRESSO™ (90 μg/kg/h) group compared to placebo at hour 60 (LS mean difference vs. placebo, −4.9).[455]

The applicant cited data from the Phase II study (202A) cited previously that ZULRESSO™ improves patients' depressive symptoms as measured by the Bech-6 Subscale, a secondary endpoint. In the Phase II study (202A), significant improvement in the core depressive symptoms of the HAM–D Bech-6 Subscale score were observed at day 30 in the ZULRESSO™ (90 μg/kg/h) group compared with the placebo group.[456]

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[447] Meltzer-Brody, S., Colquhoun, H., Riesenberg, R., Epperson, C.N., Deligiannidis, K.M., Rubinow, D.R., Li, H., Sankoh, A.J., Clemson, C., Schacterle A., Jonas, J., Kanes, S., ''Brexanolone injection in post-partum depression: two multicentre, double-blind, randomised, placebo-controlled, phase 3 trials,'' *The Lancet,* 2018, vol. 392(10152), pp. 1058–1070.

[448] Ibid.

[449] Ibid.

[450] Kanes, S., Colquhoun, H., Gunduz-Bruce, H., Raines, S., Arnold, R., Schacterle, A., Doherty, J., Epperson, C.N., Deligiannidis, K.M., Riesenberg, R., Hoffmann, E., Rubinow, D., Jonas, J., Paul, S., Meltzer-Brody, S., ''Brexanolone (SAGE–547 injection) in post-partum depression: A randomised controlled trial.'' *The Lancet,* 2017, vol. 390(10093), pp. 480–489.

[451] Meltzer-Brody, S., Colquhoun, H., Riesenberg, R., Epperson, C.N., Deligiannidis, K.M., Rubinow, D.R., Li, H., Sankoh, A.J., Clemson, C., Schacterle A., Jonas, J., Kanes, S., ''Brexanolone injection in post-partum depression: Two multicentre, double-blind, randomised, placebo-controlled, phase 3 trials,'' *The Lancet,* 2018, vol. 392(10152), pp. 1058–1070.

[452] Ibid.

[453] Kanes, S., Colquhoun, H., Gunduz-Bruce, H., Raines, S., Arnold, R., Schacterle, A., Doherty, J., Epperson, C.N., Deligiannidis, K.M., Riesenberg, R., Hoffmann, E., Rubinow, D., Jonas, J., Paul, S., Meltzer-Brody, S., ''Brexanolone (SAGE–547 injection) in post-partum depression: A randomised controlled trial.'' *The Lancet,* 2017, vol. 390(10093), pp. 480–489.

[454] Meltzer-Brody, S., Colquhoun, H., Riesenberg, R., Epperson, C.N., Deligiannidis, K.M., Rubinow, D.R., Li, H., Sankoh, A.J., Clemson, C., Schacterle A., Jonas, J., Kanes, S., ''Brexanolone injection in post-partum depression: Two multicentre, double-blind, randomised, placebo-controlled, phase 3 trials,'' *The Lancet,* 2018, vol. 392(10152), pp. 1058–1070.

[455] Ibid.

[456] Kanes, S., Colquhoun, H., Gunduz-Bruce, H., Raines, S., Arnold, R., Schacterle, A., Doherty, J., Epperson, C.N., Deligiannidis, K.M., Riesenberg, R., Hoffmann, E., Rubinow, D., Jonas, J., Paul, S., Meltzer-Brody, S., ''Brexanolone (SAGE–547 injection) in post-partum depression: A randomised controlled trial.'' *The Lancet,* 2017, vol. 390(10093), pp. 480–489.

After reviewing the information submitted by the applicant as part of its FY 2021 new technology add-on payment application for ZULRESSO™, we are concerned that the patients in the clinical trials were followed up for only 30 days, and the durability of the effects of ZULRESSO™, including whether patients in remission relapse after 30 days, is not clear. We also note that the small sample sizes of the trials and the demographic characteristics of the patients recruited for these studies may not have included or sufficiently represented populations that may be at high-risk to develop PPD, such as women who are financially or socially vulnerable and individuals with pre-existing mental illness, and it is not clear whether the study participants had time-limited PPD that might have resolved with the passage of time. It is also unclear whether the outcomes chosen for these studies (for example, test scores) translate into clinically significant observable improvements in maternal functioning and child interactions, for example, has maternal-child bonding been shown to improve as a result of the infusion. We also note that these studies compare the effects of ZULRESSO™ to placebo, and not current regimens being used to treat PPD, and do not seem to include patients who were unresponsive to existing therapies. In addition, we are concerned whether results of studies of otherwise healthy women with PPD would be generalizable to the Medicare population, in which women with PPD would likely be eligible for Medicare based on disabilities that could potentially present comorbidities for which ZULRESSO™ would not be appropriate or effective. We also note that because of possible side effects of excessive sedation or sudden loss of consciousness, ZULRESSO™ is only available through a restricted Risk Evaluation and Mitigation (REMS) program, and we are concerned whether these or other adverse events associated with ZULRESSO™ would be unsafe for women with PPD in the Medicare population. We are inviting public comments on whether ZULRESSO™ meets the substantial clinical improvement criterion, including with respect to the concerns we have raised.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for ZULRESSO™ or at the New Technology Town Hall meeting.

6. Proposed FY 2021 Applications for New Technology Add-On Payments (Alternative Pathways)

As discussed previously, for applications received for new technology add-on payments for FY 2021 and subsequent fiscal years, if a medical device is part of FDA's Breakthrough Devices Program or a product is designated by FDA as a QIDP, and received FDA marketing authorization, it will be considered new and not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and will not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. These technologies must still meet the cost criterion.

We received 10 applications for new technology add-on payments for FY 2021 under this alternative new technology add-on payment pathway. One applicant withdrew its application prior to the issuance of this proposed rule. Of the remaining nine applications, three of the technologies received a Breakthrough Device designation from FDA and six have been designated as a Qualified Infectious Disease Product (QIDP) by FDA. In accordance with the regulations under § 412.87(e), applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered.

Typically, in the annual proposed rule, we provide a summary of each application and describe any concerns we may have regarding whether the technology meets a specific new technology add-on payment criterion. As we discussed in the FY 2020 IPPS/LTCH PPS final rule, we believe it is appropriate to facilitate access to these transformative new technologies and antimicrobials as part of the Administration's commitment to addressing barriers to healthcare innovation and ensuring Medicare beneficiaries have access to critical and life-saving new cures and technologies that improve beneficiary health outcomes. To that end, to provide additional transparency and predictability with respect to these technologies, in this proposed rule we are making a proposal to approve or disapprove each of these nine applications based on whether the technology meets the cost criterion. Therefore, in this section of this rule, we provide background information on each alternative pathway application and propose whether or not each technology would be eligible for the new technology add-on payment for FY 2021 based on a discussion of whether the technology meets the cost criterion. We refer readers to section II.H.8. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) for a complete discussion of the alternative new technology add-on payment pathways for these technologies.

a. Alternative Pathway for Breakthrough Devices

(1) BAROSTIM NEO® System

CVRx submitted an application for the BAROSTIM NEO® System. According to the applicant, the BAROSTIM NEO® System is indicated for the improvement of symptoms of heart failure—quality of life, six-minute hall walk and functional status—for patients who remain symptomatic despite treatment with guideline-directed medical therapy, are NYHA Class III or Class II (who had a recent history of Class III), have a left ventricular ejection fraction ≤35%, a NT-proBNP <1600 pg/ml and excluding patients indicated for Cardiac Resynchronization Therapy (CRT) according to AHA/ACC/ESC guidelines.

The BAROSTIM NEO® System received FDA approval on August 16, 2019 and is a Breakthrough Device designated by FDA. Additionally, according to the applicant, the device was available on the market immediately upon FDA approval. Currently, the following ICD–10–PCS procedure codes can be used to uniquely identify the BAROSTIM NEO® System: 0JH60MZ (Insertion of stimulator generator into chest subcutaneous tissue and fascia, open approach) in combination with 03HK0MZ (Insertion of stimulator lead into right internal carotid artery, open approach) or 03HL0MZ (Insertion of stimulator lead into left internal carotid artery, open approach).

With regard to the cost criterion, the applicant used the FY 2018 MedPAR Limited Data Set (LDS) to assess the MS–DRGs to which potential cases representing hospitalized patients who may be eligible for treatment involving the BAROSTIM NEO® System would mapped. The applicant searched for cases with the following combination of existing ICD–10–PCS codes: 0JH60MZ in combination with 03HK0MZ or 03HL0MZ. The applicant determined its search using these procedure codes mapped to MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC,

with CC, and without CC/MCC, respectively), resulting in 71,431 total claims across these three MS–DRGs.

The applicant then removed charges for the prior technology since the BAROSTIM NEO® System will replace all of the current device charges included in the claims. The applicant explained that it removed all charges associated with the service category Medical/Surgical Supply Charge Amount, which include revenue centers 027x.

The applicant then standardized the charges and inflated the charges by applying the FY 2020 IPPS/LTCH PPS final rule outlier charge inflation factor of 1.11100 (84 FR 42629). The applicant then added the charges for the new technology by converting the cost of the device to charges by dividing the costs by the national average cost-to-charge ratio of 0.299 for implantable devices from the FY2020 IPPS Final Rule (84 FR 42179).

Based on the above, the applicant calculated a final average case-weighted standardized charge per case of $194,393 and an average case-weighted threshold of $85,559. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

According to the applicant, since the BAROSTIM NEO® System is used in heart failure patients, the applicant submitted an additional analysis to demonstrate that the technology meets the cost criterion. The applicant revised its first analysis by assessing MS–DRG 291 (Heart Failure and Shock with MCC), 292 (Heart Failure and Shock with CC), and 293 (Heart Failure and Shock without CC/MCC), 242 (Permanent Cardiac Pacemaker Implant with MCC), 243 (Permanent Cardiac Pacemaker Implant with CC), 244 (Permanent Cardiac Pacemaker Implant without CC/MCC), 222 (Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock with MCC), 223 (Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock without MCC), 224 (Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock with MCC), 225 (Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock without MCC), 226 (Cardiac Defibrillator Implant without Cardiac Catheterization with MCC) and 227 (Cardiac Defibrillator Implant without Cardiac Catheterization without MCC) using the same aforementioned ICD–10–PCS codes. The applicant used the same methodology above and calculated a final inflated average case-weighted standardized charge per case of $161,332 and an average case-weighted threshold amount of $55,697. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the technology meets the cost criterion.

We agree with the applicant that the BAROSTIM NEO® System meets the cost criterion and therefore are proposing to approve the BAROSTIM NEO® System for new technology add-on payments for FY 2021. As previously noted, there is a combination of ICD–10–PCS procedure codes that can uniquely identify cases involving the BAROSTIM NEO® System.

Based on preliminary information from the applicant at the time of this proposed rule, the cost of the BAROSTIM NEO® System is $35,000. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the BAROSTIM NEO® System would be $22,750 for FY 2021.

We are inviting public comments on whether the BAROSTIM NEO® System meets the cost criterion and our proposal to approve new technology add-on payments for the BAROSTIM NEO® System for FY 2021.

(2) NanoKnife® System

Angiodynamics submitted an application for new technology add-on payments for the NanoKnife® System for FY 2021. The applicant is seeking new technology-add on payments for the use of the NanoKnife® System with six outputs for the treatment of Stage III pancreatic cancer. We note that FDA has not yet granted market approval of the NanoKnife® System for use in the treatment of pancreatic cancer. We also note that the NanoKnife® System has been previously approved by FDA for the use for surgical ablation of soft tissue. Per the applicant, the Nanoknife® System is a medical device consisting of a dedicated generator and specialized electrode probes currently used for inpatient hospital ablation procedures for surgical treatment of soft tissue ablation procedures. The NanoKnife® System is considered a FDA class II device when indicated for soft tissue ablation.

The applicant states that the NanoKnife® System delivers a series of high voltage direct current electrical pulses between at least two electrode probes placed within a target area of tissue. The electrical pulses produce an electric field which induces electroporation on cells within the target area. The number of electrodes used is dependent on the size and shape of the tumor, and the individual patient's clinical needs.

Electroporation is a technique in which an electrical field is applied to cells in order to increase the permeability of the cell membranes through the formation of nanoscale defects in the lipid bilayer. The result is creation of nanopores in the cell membrane and disruption of intra-cellular homeostasis, ultimately causing cell death. The applicant stated that after delivering a sufficient number of high voltage pulses, the cells surrounded by the electrodes will be irreversibly damaged. This mechanism, which causes permanent cell damage, is referred to as Irreversible Electroporation (IRE). Per the applicant, benefits of IRE over other ablation methods include: (1) Localized ablation of targeted tissue; (2) lack of damaging heat-sink effect often seen with traditional thermal ablation techniques; and (3) preservation of critical anatomic structures in the vicinity of the ablation. Furthermore, according to the applicant, in studies to date, the NanoKnife® System has been shown to be safe and effective in patients presenting with unresectable tumors, who, given current treatment standards, have few viable treatment options.

The NanoKnife® System with six outputs for the treatment of Stage III pancreatic cancer received FDA Breakthrough Device designation on January 18, 2018 and approval of an FDA investigational device exemption (IDE G180278) on March 28, 2019. We note, and as discussed above, that although the NanoKnife® System received FDA Breakthrough Device designation for treatment of pancreatic cancer, FDA has not yet market approved or cleared the NanoKnife® System for use in the treatment of pancreatic cancer. The NanoKnife® System is currently being used for the treatment of Stage III pancreatic cancer in the DIRECT clinical trial in which the first patient was enrolled on May 13, 2019. Completion of the clinical trial is

not expected until approximately December 2023.[457]

The applicant noted that earlier iterations of the NanoKnife® System indicated for the surgical ablation of soft tissue were available on the market after FDA clearances in 2008 and 2015. According to the applicant, NanoKnife 3.0®, the most recent iteration of the NanoKnife® System device consisting of improvements and advancements as compared to prior versions of the device, was cleared by FDA on June 19, 2019 for the surgical ablation of soft tissue and per the applicant became commercially available on the U.S. market in June 2019. Consistent with prior versions of the device, NanoKnife 3.0® is labeled for soft tissue ablation. We note that since the earlier versions of the NanoKnife® System have been available commercially on the U.S. market following FDA clearances in 2008 and 2015, these versions are not considered new. As mentioned above, under the first criterion, a specific medical service or technology will be considered ''new'' for purposes of new medical service or technology add-on payments until such time as Medicare data are available to fully reflect the cost of the technology in the MS–DRG weights through recalibration. Therefore, the indication associated with the device during that timeframe, soft tissue ablation, would not be relevant for purposes of the new technology add-on payment application for FY 2021. Only the use of the NanoKnife® System with six outputs for the treatment of Stage III pancreatic cancer, for which the applicant submitted its application for new technology-add on payments for FY 2021, and the FDA Breakthrough Device designation it received for that use, are relevant for purposes of the new technology add-on payment application for FY 2021.

According to the applicant, ICD–10–PCS procedure codes 0F5G0ZF (Destruction of pancreas using irreversible electroporation, open approach), 0F5G3ZF (Destruction of pancreas using irreversible electroporation, percutaneous approach), and 0F5G4ZF (Destruction of pancreas using irreversible electroporation, percutaneous endoscopic approach) may be used to distinctly identify cases involving the NanoKnife® System because the NanoKnife® System is currently the only device used for irreversible electroporation in the United States.

The applicant conducted the following analysis to demonstrate that the technology meets the cost criterion. The applicant used the FY 2018 MedPAR Limited Data Set (LDS) to identify the MS–DRGs to which potential cases representing hospitalized patients who may be eligible for treatment involving the NanoKnife® System would be mapped. The applicant searched for cases reporting the following predecessor ICD–10–PCS codes: 0F5G0ZZ (Destruction of pancreas, open approach), 0F5G3ZZ (Destruction of pancreas, percutaneous approach) and 0F5G4ZZ (Destruction of pancreas, percutaneous endoscopic approach). According to the applicant, this resulted in 40 cases mapped to MS–DRGs 405, 406, and 407 (Pancreas, Liver and Shunt Procedures with MCC, with CC, and without CC/MCC, respectively). The applicant noted that cases eligible for use of the NanoKnife® System would likely map to MS–DRGs 628, 629, or 630 (Other Endocrine, Nutritional and Metabolic O.R. procedures with MCC, with CC, and without CC/MCC, respectively) as well but none of the 40 cases above mapped to these MS–DRGs. However, the applicant stated that had there been cases assigned to MS–DRGs 628, 629, or 630, these would have been selected as well. The applicant also noted that cases where the open approach Whipple procedure (ICD–10–PCS code 0FBG0ZZ (Excision of pancreas, open approach)) was coded were removed, as according to the applicant it is unlikely this procedure would be performed in conjunction with IRE because the Whipple procedure is an extensive surgical procedure that may not be necessary with IRE. The applicant only disclosed the percentage of cases assigned to MS–DRG 406 because, according to the applicant, the number of cases assigned to MS–DRGs 405 and 407 was less than 12 for each MS–DRG, making the exact percentage for these two MS–DRGs unavailable.

The applicant examined associated charges per MS–DRG. According to the applicant, since the 40 cases mapped to MS–DRGs 405, 406 and 407 could include charges for various technologies for destruction of pancreatic tumors, and in order to exclude charges for prior technology, the applicant removed all charges billed to the medical supplies cost center for MS–DRGs 405, 406 and 407, as this cost center could include charges associated with use of various predecessor technologies for destruction of pancreatic tumors. The applicant noted it did not remove charges related to the predecessor technology as it believes that remaining charges associated with the cases would stay the same. According to the applicant, related charges consist of operating room, routine, intensive care, drug, radiology and Computed Tomography charges. The applicant then standardized the charges for each case and inflated each case's charges by applying the FY 2020 IPPS/LTCH PPS final rule outlier charge inflation factor of 1.11100 (84 FR 42629). The applicant then added the charges for the Nanoknife® System by dividing the costs of the device and required ancillary supplies per patient by the national average cost-to-charge ratio of 0.299 for implantable devices from the FY 2020 IPPS Final Rule (84 FR 42179). The applicant calculated a final inflated average case-weighted standardized charge per case of $175,836 and an average case-weighted threshold amount of $102,842. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant maintained that the technology met the cost criterion.

We agree with the applicant that it meets the cost criterion. As noted previously, subject to our proposed conditional approval process for technologies for which an application is submitted under the alternative pathway for certain antimicrobial products, applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. As also summarized previously, the applicant is seeking new technology-add on payments for the use of the NanoKnife® System with six outputs for the treatment of Stage III pancreatic cancer, and it is only that use, and the FDA Breakthrough Device designation it received for that use, that are relevant for purposes of the new technology add-on payment application for FY 2021. Therefore, subject to the NanoKnife® System receiving FDA clearance or approval for use in the treatment of Stage III pancreatic cancer by July 1, 2020, we are proposing to approve the NanoKnife® System for new technology add-on payments for FY 2021.

Based on preliminary information from the applicant at the time of this proposed rule, the cost of the NanoKnife® System is $11,086. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit

[457] *https://clinicaltrials.gov/ct2/show/study/NCT03899636?term=NanoKnife&draw=2&rank=6.*

new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the NanoKnife® System would be $7,205.90 for FY 2021.

We are inviting public comments on whether the NanoKnife® System meets the cost criterion and our proposal to approve new technology add-on payments for the NanoKnife® System for FY 2021, subject to the NanoKnife® System receiving FDA clearance or approval for use in the treatment of Stage III pancreatic cancer by July 1, 2020.

(3) Optimizer System

Impulse Dynamics submitted an application for The Optimizer® System (QFV). The Optimizer® System is intended for the treatment of chronic heart failure in patients with advanced symptoms that have normal QRS duration and are not indicated for cardiac resynchronization therapy.

Per the applicant, the Optimizer System consists of three components. First, the Optimizer Rechargeable Implantable Pulse Generator (IPG) is designed for subcutaneous implant and delivers cardiac contractility modulation to the heart via two standard pacing leads attached to the right ventricular septum. Second, the Optimizer Mini Charger recharges the Optimizer IPG. Finally, the Omni II Programmer with Omni SMART Software gives a qualified healthcare professional the ability to program the Optimizer IPG over a large range of clinical settings.

The applicant explained that the Optimizer IPG is implanted in the right pre-pectoral region, similar to cardiac rhythm management devices. According to the applicant, the procedure is performed in a cardiac catheterization laboratory under fluoroscopic guidance with the patient under light sedation. The applicant stated that since three intracardiac leads are used, subclavian venous access is preferred over access via the axillary or cephalic vein. The applicant stated that the Optimizer IPG is connected to the heart via two standard implantable pacing leads that are each placed into the right ventricular septum.

With respect to the newness criterion, the applicant indicated that the FDA granted Breakthrough Device designation for the Optimizer System on March 21, 2019. The applicant received FDA premarket approval for the two-lead Optimizer System, which included placement of the two leads in the right ventricular septum, on October 23, 2019. The device was available in the market immediately following FDA approval.

The applicant asserted that the current ICD–10–PCS codes 0JH60AZ (Insertion of contractility modulation device into chest subcutaneous tissue and fascia, open approach), 0JH63AZ (Insertion of contractility modulation device into chest subcutaneous tissue and fascia, percutaneous approach), 0JH80AZ (Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, open approach) and 0JH83AZ (Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, percutaneous approach) identify the Optimizer System.

With regard to the cost criterion, the applicant conducted an analysis using the FY 2018 MedPAR Limited Data Set (LDS) to demonstrate that the Optimizer System meets the cost criterion.

The applicant first searched the FY 2018 MedPAR data for cases reporting the procedure codes listed in this section to identify potential cases representing hospitalized patients who may be eligible for treatment using the Optimizer® System. The applicant limited its search to MS–DRG 245 (AICD Generator Procedures), which it asserts is the typical MS–DRG assignment for implanting a contractility modulation device. The applicant identified 2,049 cases that met the criterion of having at least one of the following relevant ICD–10–PCS procedure codes:

ICD-10-PCS Procedure Codes Describing a Contract Modulation Device Implant	
ICD-10-PCS Code	**ICD-10-PCS Description**
0JH60AZ	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, open approach
0JH63AZ	Insertion of contractility modulation device into chest subcutaneous tissue and fascia, percutaneous approach
0JH80AZ	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, open approach
0JH83AZ	Insertion of contractility modulation device into abdomen subcutaneous tissue and fascia, percutaneous approach

ICD-10-PCS Procedure Codes Describing Insertion of Leads	
ICD-10-PCS Code	**ICD-10-PCS Description**
02HK0MZ	Insertion of cardiac lead into right ventricle, open approach
02HK3MZ	Insertion of cardiac lead into right ventricle, percutaneous approach
02H60MZ	Insertion of cardiac lead into right atrium, open approach
02H63MZ	Insertion of cardiac lead into right atrium, percutaneous approach

The applicant determined an average unstandardized charge per case of $180,319. The applicant then removed all charges for prior technology by removing charges associated with the service categories Prosthetic/Orthotic (revenue center 0274), Pacemakers (revenue center 0275) and other implantables (revenue center 0278), as the applicant believed the Optimizer® System will typically not be implanted concomitantly with other devices during the hospital admission. The applicant then standardized the charges and applied the FY 2020 IPPS/LTCH PPS final rule outlier charge inflation factor of 1.11100 (84 FR 42629) to update the charges from FY 2018 to FY 2020.

The applicant added the charges for the new technology by dividing its cost per patient by the national average cost-to-charge ratio of 0.299 for implantable devices from the FY2020 IPPS Final Rule (84 FR 42179).

The applicant calculated a final inflated average case-weighted standardized charge per case of $190,167, which it stated exceeded the average case-weighted threshold amount of $148,002 by $42,165.

The applicant also conducted a subsequent analysis that only included

patients with a diagnosis of heart failure. The applicant once again limited its search to MS–DRG 245 and refined its sample by including only cases with one of the ICD–10–PCS procedure codes listed previously and an ICD–10–CM diagnosis code from Category I50 (Heart Failure) on the claim. This resulted in 1,698 cases with an average unstandardized charge per case of $183,243. After following the same order of operations as the first analysis, the final inflated average case weighted standardized charge per case was $192,237, which exceeded the average case weighted threshold amount of $148,002. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount under both analyses described previously, the applicant maintains that the technology meets the cost criterion.

We agree with the applicant that the technology meets the cost criterion and therefore are proposing to approve the Optimizer® System for new technology add-on payments for FY 2021. As noted above, the applicant asserted that ICD–10–PCS codes 0JH60AZ, 0JH63AZ, 0JH80AZ and 0JH83AZ identify the Optimizer® System.

Based on preliminary information from the applicant at the time of this proposed rule, the cost of the Optimizer® System is $23,000. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the Optimizer® System would be $14,950 for FY 2021.

We are inviting public comments on whether the Optimizer® System meets the cost criterion and our proposal to approve new technology add-on payments for the Optimizer® System for FY 2021.

b. Alternative Pathways for Qualified Infectious Disease Products (QIDPs)

(1) Cefiderocol (Fetroja)

Shionogi & Co. Ltd (Company) submitted an application for Cefiderocol (Fetroja), a β-lactam antibiotic indicated for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, caused by the following susceptible GN pathogens: *Escherichia coli* (including with concurrent bacteremia), *Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, Citrobacter freundii, Enterobacter cloacae, Morganella morganii,* and *Serratia marcescens.* Per the applicant, Cefiderocol should be used to treat infections where limited or no alternative treatment options are available and where cefiderocol is likely to be an appropriate treatment option, which may include use in patients with infections caused by documented or highly suspected CR and/or multidrug-resistant GN pathogens.

The applicant describes Cefiderocol as an injectable siderophore cephalosporin. The applicant asserts that the principal antibacterial/bactericidal activity of Cefiderocol occurs with inhibiting Gram-negative (GN) bacterial cell wall synthesis by binding to penicillin-binding proteins. The applicant contends that Cefiderocol is unique in that it can enter the bacterial periplasmic space (in addition to the typical entry point via porin channels) as a result of its siderophore-like property, has enhanced stability to β-lactamases, and has activity limited to GN aerobic bacteria only.

Per the applicant, cUTIs are the second leading cause of hospitalization in the elderly and have substantial morbidity and worse outcomes if the causative pathogens are carbapenem-resistant (CR). According to the applicant, bloodstream infection (BSI) is often associated with cUTI, known as urosepsis, with an associated mortality rate of 9 to 31 percent. The applicant asserts that patients who develop cUTI due to a CR pathogen are at greater risk for prolonged hospital stays and progression to a BSI or urosepsis. The applicant stated that CR is a growing problem in the US and around the world, with increasing infections due to strains that are resistant to most or all currently available antibiotics. The applicant further states that, compared to susceptible pathogens, CR pathogens cause prolonged hospital and intensive care unit (ICU) stays, worse discharge status, and greater mortality.

Cefiderocol is designated as a Qualified Infectious Disease Product (QIDP) and received FDA approval on November 19, 2019. However, according to the applicant, Cefiderocol was not commercially available until February 24, 2020 due to the finalization of the materials associated with the commercial launch of a drug, which could not be completed until the final label with the FDA was determined. The applicant noted that there are currently no ICD–10–PCS procedure codes that could be used to uniquely identify the administration of Cefiderocol. The applicant has submitted a request for approval for a new ICD–10–PCS code for consideration at the March 2020 ICD–10 C&M Meeting.

With regard to the cost criterion, the applicant conducted two analyses based on 100% and 75% of identified claims. For both scenarios, the applicant used the FY 2018 MedPAR Limited Data Set (LDS) to assess the MS–DRGs to which potential cases representing hospitalized patients who may be eligible for Cefiderocol treatment would be mapped. The applicant identified eligible cases by searching the FY 2018 MedPAR for cases reporting one of the following ICD–10–CM codes:

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ICD-10-CM Code	Description
K68.11	Postprocedural retroperitoneal abscess
N10	Acute pyelonephritis
N11.1	Chronic obstructive pyelonephritis
N12	Tubulo-interstitial nephritis, not specified as acute or chronic
N13.6	Pyonephrosis
N15.1	Renal and perinephric abscess
N28.84	Pyelitis cystica
N28.85	Pyeloureteritis cystica
N30.00	Acute cystitis without hematuria
N30.01	Acute cystitis with hematuria
N30.80	Other cystitis without hematuria
N30.81	Other cystitis with hematuria
N30.90	Cystitis, unspecified without hematuria
N39.0	Urinary tract infection, site not specified
N41.0	Acute prostatitis
N99.521	Infection of incontinent external stoma of urinary tract
O03.38	Urinary tract infection following incomplete spontaneous abortion
O03.88	Urinary tract infection following complete or unspecified spontaneous abortion
O04.88	Urinary tract infection following (induced) termination of pregnancy
O07.38	Urinary tract infection following failed attempted termination of pregnancy
O08.83	Urinary tract infection following an ectopic and molar pregnancy
O23.02	Infections of kidney in pregnancy, second trimester
O23.03	Infections of kidney in pregnancy, third trimester
O23.30	Infections of other parts of urinary tract in pregnancy, unspecified trimester
O23.40	Unspecified infection of urinary tract in pregnancy, unspecified trimester
O23.41	Unspecified infection of urinary tract in pregnancy, first trimester
O23.42	Unspecified infection of urinary tract in pregnancy, second trimester
O23.43	Unspecified infection of urinary tract in pregnancy, third trimester
O86.20	Urinary tract infection following delivery, unspecified
O86.21	Infection of kidney following delivery
O86.29	Other urinary tract infection following delivery
T81.4XXA	Infection following a procedure, initial encounter
T83.511A	Infection and inflammatory reaction due to indwelling urethral catheter, initial encounter
T83.512A	Infection and inflammatory reaction due to nephrostomy catheter, initial encounter
T83.518A	Infection and inflammatory reaction due to other urinary catheter, initial encounter
T83.590A	Infection and inflammatory reaction due to implanted urinary neurostimulation device, initial encounter
T83.591A	Infection and inflammatory reaction due to implanted urinary sphincter initial encounter
T83.592A	Infection and inflammatory reaction due to implanted indwelling ureteral stent initial encounter
T83.593A	Infection and inflammatory reaction due to other urinary stents, initial encounter
T83.598A	Infection and inflammatory reaction due to other prosthetic device, implant and graft in urinary system, initial encounter
T83.59XA	Infection and inflammatory reaction due to prosthetic device, implant and graft in urinary system, initial encounter
T83.61XA	Infection and inflammatory reaction due to other prosthetic device, due to implanted penile prosthesis, initial encounter
T83.62XA	Infection and inflammatory reaction due to other prosthetic device, due to implanted testicular prosthesis, initial encounter
T83.69XA	Infection and inflammatory reaction due to other prosthetic device, implant and graft in genital track, initial encounter
T86.13	Kidney transplant infection

BILLING CODE 4120–01–C

Under the first scenario of 100 percent of cases, the applicant identified 1,461,784 cases mapping to 656 MS–DRGs. Under the second scenario of 75 percent of cases, the applicant identified 1,097,594 cases mapping to 53 MS–DRGs. The applicant standardized the charges after calculating the average case-weighted unstandardized charge per case for both scenarios and removing 50 percent of charges associated with the drug revenue centers 025x, 026x, and 063x under both scenarios. (Per the applicant, Cefiderocol is expected to replace some of the drugs that would otherwise be utilized to treat these patients. The applicant stated that it believes 50 percent of these total charges to be a conservative estimate as other drugs will still be required for these patients during their hospital stay.) The applicant then applied an inflation factor of 11.1 percent, which was the two-year outlier charge inflation factor used in the FY 2020 IPPS/LTCH PPS final rule, to update the charges from FY 2018 to FY 2020. The applicant then added charges for Cefiderocol by dividing the total average hospital cost of Cefiderocol by the national average cost-to-charge ratio (0.189) for drugs published in the FY 2020 IPPS/LTCH PPS final rule.

The applicant calculated a final inflated average case-weighted standardized charge per case of $116,131 for the first scenario and $106,037 for the second scenario and an average case-weighted threshold amount of $55,885 for the first scenario and $50,887 for the second scenario.

Because the final inflated average case-weighted standardized charge per case for each scenario exceeds the average case-weighted threshold amount for each scenario, the applicant asserted that the technology meets the cost criterion.

We agree with the applicant that Cefiderocol meets the cost criterion and therefore are proposing to approve Cefiderocol for new technology add-on payments for FY 2021. As previously noted, the applicant has submitted a request for approval for a new ICD–10–PCS procedure code to uniquely identify cases of Cefiderocol. We anticipate additional coding information will be available for the final rule.

In its application, the applicant stated that the cost of Cefiderocol is $10,559.81. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under 412.88(a)(2), we limit new technology add-on payments for QIDPs to the lesser of 75 percent of the costs of the new medical service or technology, or 75 percent of the amount by which the costs of the case exceed the MS–DRG payment. As a result, we are proposing that the maximum new technology add-on payment for a case involving the administration of Cefiderocol would be $7,919.86 for FY 2021 (that is 75 percent of the average cost of the technology).

We are inviting public comments on whether Cefiderocol meets the cost criterion and our proposal to approve new technology add-on payments for Cefiderocol for FY 2021.

(2) Contepo

CONTEPO™ (fosfomycin for injection), is intended for treatment of complicated urinary tract infections (cUTI) and is designated by FDA as a QIDP. In October 2018, Nabriva Therapeutics submitted a New Drug Application (NDA) to the US–FDA seeking marketing approval of IV fosfomycin for injection (ZTI–01) for the treatment of patients 18 years and older with cUTI including acute pyelonephritis (AP) caused by designated susceptible bacteria. The applicant noted that once approved, CONTEPO will represent the first FDA-approved IVepoxide antibiotic in the United States.

On April 30, 2019, Nabriva received a Complete Response Letter (CRL) from FDA for the NDA seeking marketing approval of CONTEPO (fosfomycin) for injection. The applicant stated that the CRL from FDA requests that Nabriva address issues related to facility inspections and manufacturing deficiencies at one of Nabriva's contract manufacturers prior to FDA approving the NDA. Nabriva has resubmitted its NDA to FDA with FDA setting a Prescription Drug User Fee Act (PDUFA) goal date of June 19, 2020 for the completion of its review of the NDA.

The applicant applied for and received a unique ICD–10–PCS procedure code to identify cases involving the administration of CONTEPO™ in 2019. Effective October 1, 2019, CONTEPO™ administration can be identified by ICD–10–PCS procedure codes XW033K5, (Introduction of Fosfomycin anti-infective into peripheral vein, percutaneous approach, new technology group 5) and XW043K5 (Introduction of Fosfomycin anti-infective into central vein, percutaneous approach, new technology group 5), which the applicant states are unique to CONTEPO administration.

With regard to the cost criterion, the applicant used the FY 2018 MedPAR Limited Data Set (LDS) to assess the MS–DRGs to which potential cases representing hospitalized patients who may be eligible for treatment involving CONTEPO™ would most likely be mapped. According to the applicant, CONTEPO™ is anticipated to be indicated for the treatment of hospitalized patients who have been diagnosed with complicated urinary tract infections (cUTIs). The applicant identified 199 ICD–10–CM diagnosis code combinations that identify hospitalized patients who have been diagnosed with a cUTI. Searching the FY 2018 MedPAR data file for these ICD–10–CM diagnosis codes resulted in a total of 684,664 potential cases that span 570 unique MS–DRGs, 522 of which contained more than 10 cases. The applicant excluded MS–DRGs with minimal volume (that is, 10 cases or less) from the cohort of the analysis (a total of 252 cases and 48 MS–DRGs), and this resulted in a total of 684,412 cases across 522 MS–DRGs.

The applicant examined associated charges per MS–DRG and removed charges for potential antibiotics that may be replaced by the use of CONTEPO™. Specifically, the applicant identified 5 antibiotics currently used for the treatment of patients who have been diagnosed with a cUTI and calculated the cost of each of these drugs for administration over 14 day inpatient hospitalization. Because patients who have been diagnosed with a cUTI would typically only be treated with one of these antibiotics at a time, the applicant estimated an average of the 14-day cost for the 5 antibiotics. The applicant then converted the cost to charges by dividing the costs by the national average CCR of 0.189 for drugs from the FY 2020 IPPS/LTCH PPS final rule (84 FR 42179).

The applicant then standardized the charges for each case and inflated each case's charges by applying the FY 2020 IPPS/LTCH PPS final rule outlier charge inflation factor of 1.11100 (84 FR 42629). The applicant then added the charges for the new technology by calculating the per-day cost per patient. The applicant noted that the duration of therapy of up to 14 days (patients that had a cUTI with concurrent bacteremia) is consistent with the prospective prescribing information, and that it used this 14-day duration of therapy to calculate total inpatient cost. The applicant then converted these costs to charges by dividing the costs per patient by the national average cost-to charge ratio of 0.189 for drugs from the FY 2020 IPPS/LTCH PPS final rule (84 FR 42179). The applicant calculated a final inflated average case-weighted standardized charge per case of $75,533 and a case weighted threshold of $55,447. Because the final inflated average case-weighted standardized charge per case for CONTEPO™ exceeded the average case-weighted threshold amount, the applicant maintained it meets the cost criterion.

As summarized, the applicant used a 14-day duration of therapy to calculate total inpatient cost for purposes of its cost analysis. However, the applicant noted that the average number of days a patient would be administered CONTEPO™ will most likely fall between 10–14 days of therapy given the current guideline recommendations. Of these treatment days, the applicant noted that nearly all would occur during the inpatient hospital stay. Consistent with our historical practice, we believe the new technology add-on payment for CONTEPO™, if approved, would be based on the average cost of the technology and not the maximum. For example, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53358), we approved new technology add-on payments for DIFICID™ based on the average dosage of 6.2 days rather than the maximum 10 day dosage. Without further information from the applicant regarding the average number of days CONTEPO™ is administered, we believe using the middle ground of 12.5 days, based on the 10–14 day period indicated by the applicant, is appropriate for this analysis to determine the average number of days CONTEPO™ is administered in the hospital. To assess whether the technology would meet the cost criterion using an average cost for the

technology based on this 12.5-day period for CONTEPO™ administration, we converted the costs to charges by dividing the costs per patient by the national average cost-to charge ratio of 0.189 for drugs from the FY 2020 IPPS/LTCH PPS final rule (84 FR 42179). Based on data from the applicant, this resulted in a final inflated average case-weighted standardized charge per case of $73,548 which exceeds the case weighted threshold of $55,447.

Because of the large number of cases included in this cost analysis, the applicant supplemented the analysis as described previously with additional sensitivity analyses. In these analyses, the previous cost analysis was repeated using only the top 75 percent of cases, the top 20 MS–DRGs, and the top 10 MS–DRGs. In these three additional sensitivity analyses, the final inflated average case-weighted standardized charge per case for CONTEPO™ of $64,019, $62,486 and $61,158 exceeded the average case-weighted threshold amount of $51,085, $50,704 and $49,889, respectively. We note that the applicant did not use the thresholds from the correction notice to case weight the charges, however the variance is minimal with the final inflated average case-weighted standardized charge per case well in excess of the case weighted threshold amounts. Because the final inflated average case-weighted standardized charge per case for CONTEPO™ exceeded the average case-weighted threshold amount, the applicant asserts that CONTEPO™ meets the cost criterion.

We believe that CONTEPO™ meets the cost criterion and therefore are proposing to approve CONTEPO™ for new technology add-on payments for FY 2021. As previously noted, the applicant has received a unique ICD–10–PCS procedure code to identify cases involving the administration of CONTEPO™.

As discussed previously, without further information from the applicant regarding the average number of days CONTEPO™ is administered, we believe using a 12.5 day duration of therapy is a reasonable approach for estimating the average cost of the technology. Based on preliminary information from the applicant at the time of this proposed rule, the cost of CONTEPO™ administered over 12.5 days is $3,125. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under 412.88(a)(2), we limit new technology add-on payments for QIDPs to 75 percent of the costs of the new medical service or technology, or 75 percent of the amount by which the costs of the case exceed the MS–DRG payment. As a result, we are proposing that the maximum new technology add-on payment for a case involving the administration of CONTEPO™ would be $2,343.75 for FY 2021 (that is 75 percent of the average cost of the technology).

We are inviting public comments on whether CONTEPO™ meets the cost criterion and our proposal to approve new technology add-on payments for CONTEPO™ for FY 2021.

(3) NUZYRA® for Injection

Paratek Pharmaceuticals submitted an application for new technology add-on payments for NUZYRA® (omadacycline) for Injection for FY 2021. According to the applicant, NUZYRA® for Injection is a tetracycline class antibacterial indicated for the treatment of adult patients with the following infections caused by susceptible microorganisms:

- Community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible isolates), Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumophila, Mycoplasma pneumoniae, and Chlamydophila pneumoniae.
- Acute bacterial skin and skin structure infections (ABSSSI) caused by the following susceptible microorganisms: Staphylococcus aureus (methicillin susceptible and resistant isolates), Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp. (includes S. anginosus, S. intermedius, and S. constellatus), Enterococcus faecalis, Enterobacter cloacae, and Klebsiella pneumoniae.

The applicant explained that NUZYRA® for Injection is supplied as a lyophilized powder in a single-dose colorless glass vial, with each vial containing 100 mg of NUZYRA® (equivalent to 131 mg omadacycline tosylate). 100-mg single dose vials are packaged in cartons of 10. The NDC number is 71715–001–02. Additionally, the applicant noted that while an oral formulation of NUZYRA® is available, NUZYRA® can also be administered through intravenous infusion. Providers may determine which method of administration is clinically appropriate for each patient. Adult patients with community-acquired bacterial pneumonia (CABP) must receive their initial loading dose of NUZYRA® via intravenous infusion. The applicant specified that NUZYRA® for Injection should not be administered with any solution containing multivalent cations, for example, calcium and magnesium, through the same intravenous line. Co-infusion with other medications has not been studied. The applicant conveyed that for treatment of adults with CABP, the recommended dosage regimen of NUZYRA® for Injection is as follows (Use NUZYRA for injection administered by intravenous infusion for the loading dose in CABP patients):

Loading Dose	Maintenance Does	Treatment Duration
200-mg by intravenous infusion over 60 minutes on the first day.	100-mg by intravenous infusion once daily infused over 30 minutes.	7 to 14 days

For treatment of adults with ABSSSI, the recommended dosage regimen of NUZYRA® for injection is as follows (Use NUZYRA® for injection administered by intravenous infusion or NUZYRA® tablets orally administered for the loading dose in ABSSSI patients):

Loading Dose	Maintenance Does	Treatment Duration
200-mg by intravenous infusion over 60 minutes on the first day.	100-mg by intravenous infusion once daily infused over 30 minutes.	7 to 14 days

Finally, the applicant indicated that no dose adjustment is warranted in patients with renal or hepatic impairment.

According to the applicant, NUZYRA® for Injection was submitted for FDA approval under a New Drug Application (identified as NDA 209817). After Fast Track and Priority Review consideration, NUZYRA® for Injection received FDA approval on October 2, 2018. According to information provided by the applicant, NUZYRA® for Injection was designated as a QIDP and granted priority review. According to the applicant, NUZYRA® for Injection became commercially available in February 2019. The applicant explained that the delay in commercial availability was due to an effort to prepare the distribution and supply channel (pharmacies and wholesalers) and to prepare for a full promotional launch. The applicant noted that there are currently no ICD–10–PCS procedure codes that uniquely identify the use of NUZYRA® for Injection. However, the applicant stated in the absence of a unique code for NUZYRA® that providers could use ICD–10–PCS procedure codes 3E03329 (Introduction of other anti-infective into peripheral vein, percutaneous approach) or 3E04329 (Introduction of other anti-infective into central vein, percutaneous approach). The applicant has submitted a request for approval for a new ICD–10–PCS procedure code to uniquely identify NUZYRA® for Injection for administration in FY 2021.

With regard to the cost criterion, the applicant used the FY 2018 MedPAR Limited Data Set (LDS) to identify potential cases that may be eligible for treatment involving NUZYRA® for Injection. To ensure appropriate discharges were used from the dataset, the following edits were made:

- Claims paid by a Managed Care Organization were removed.
- Duplicated records with the same beneficiary ID, provider, admission data, and discharge date were removed.
- Interim claims were combined into discharge records.
- Discharges with covered charges of zero dollars and discharges with zero covered days were removed.
- Discharges from IPPS hospitals, as determined by the FY 2020 IPPS Impact File and discharges with discharge dates from October 1, 2017 to September 30, 2018 were included.
- Statistical outliers with standard charges that were outside of the range of +/− 3 standard deviations from the geometric mean standardized charge by MS–DRG were removed.

After these edits were made, the applicant selected discharges that had a primary or secondary diagnosis for ABSSSI or CABP, using a wide list of ICD–10–PCS codes, which resulted in a total of 1,745,649 discharges. Using these 1,745,649 discharges, 37 MS–DRGs were selected based on one of the following criteria:

- MS–DRGs with the highest volume of discharges with a primary or secondary diagnosis for ABSSSI or CABP (which represent 70 percent of all discharges with ABSSSI or CABP).
- MS–DRGs with at least two-thirds of discharges with a primary or secondary diagnosis of ABSSSI or CABP.

Using this method, the applicant identified 1,226,429 total cases which mapped to the following 37 unique MS–DRGs:

MS-DRG	DESCRIPTION
064	Intracranial Hemorrhage or Cerebral Infarction with MCC
166	Other Respiratory System O.R. Procedures with MCC
177	Respiratory Infections and Inflammations with MCC
178	Respiratory Infections and Inflammations with CC
189	Pulmonary Edema and Respiratory Failure
190	Chronic Obstructive Pulmonary Disease with MCC
193	Simple Pneumonia and Pleurisy with MCC
194	Simple Pneumonia and Pleurisy with CC
195	Simple Pneumonia and Pleurisy without CC/MCC
208	Respiratory System Diagnosis with Ventilator Support <=96 Hours
280	Acute Myocardial Infarction, Discharged Alive with MCC
291	Heart Failure and Shock with MCC
308	Cardiac Arrhythmia and Conduction Disorders with MCC
314	Other Circulatory System Diagnoses with MCC
377	G.I. Hemorrhage with MCC
571	Skin Debridement with CC
572	Skin Debridement without CC/MCC
574	Skin Graft For Skin Ulcer or Cellulitis with CC
580	Other Skin, Subcutaneous Tissue and Breast Procedures with CC
602	Cellulitis with MCC
603	Cellulitis without MCC
616	Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders with MCC
617	Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders with CC
623	Skin Grafts and Wound Debridement for Endocrine, Nutritional and Metabolic Disorders with CC
638	Diabetes with CC
682	Renal Failure with MCC
683	Renal Failure with CC
689	Kidney and Urinary Tract Infections with MCC
690	Kidney and Urinary Tract Infections without MCC
698	Other Kidney and Urinary Tract Diagnoses with MCC
853	Infectious and Parasitic Diseases with O.R. Procedure with MCC
854	Infectious and Parasitic Diseases with O.R. Procedure with CC
857	Postoperative or Post-Traumatic Infections with O.R. Procedure with CC
863	Postoperative and Post-Traumatic Infections without MCC
870	Septicemia or Severe Sepsis with MV >96 Hours
871	Septicemia or Severe Sepsis without MV >96 Hours with MCC
872	Septicemia or Severe Sepsis without MV >96 Hours without MCC

Next, using the cases mapping to these selected MS–DRGs, the applicant removed pharmacy charges for other drugs and standardized the charges. Then, the applicant inflated the standardized charges from FY 2018 to FY 2020 using a 2-year charge inflation factor of 11.1 percent, based on the FY 2020 IPPS/LTCH PPS final rule (84 FR 42629).

The applicant estimated the cost of NUZYRA® for Injection based on an average inpatient stay of 5 days in the clinical trial.[458] Some patients may be required to stay longer than 5 days, resulting in increased charges. Using a loading dose for day 1 and maintenance doses in days 2 through 5 results in use of 6 vials. Each vial costs $345, resulting in a total cost for the new technology of $2,070. The applicant estimated charges for the drug by dividing the cost by the national average cost-to-charge (CCR) for drugs of 0.189, as set forth in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42179). This resulted in estimated charges of $10,952. The applicant then added $10,952 of charges for the drug which resulted in a final inflated average case-weighted standardized charge per case of $58,922. The applicant determined an average case-weighted threshold amount of $53,899. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant maintained that the technology met the cost criterion.

[458] Doe, et al., ''Reducing mortality in disease X population: analysis,'' *JAMA* 2019, vol. 2(5), pp. 12–23.

We agree with the applicant that it meets the cost criterion and therefore are proposing to approve NUZYRA® for Injection for new technology add-on payments for FY 2021. As previously noted, the applicant has submitted a request for approval for a new ICD–10–PCS procedure code to uniquely identify cases of NUZYRA® for Injection. We anticipate additional coding information will be available for the final rule.

Based on preliminary information from the applicant at the time of this proposed rule, the cost of NUZYRA® for Injection is $2,070. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments for QIDPs to 75 percent of the costs of the new medical service or technology, or 75 percent of the amount by which the costs of the case exceed the MS–DRG payment. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of NUZYRA® for Injection would be $1,552.50 for FY 2021 (that is 75 percent of the average cost of the technology).

We are inviting public comments on whether NUZYRA® for Injection meets the cost criterion and our proposal to approve new technology add-on payments for NUZYRA® for Injection for FY 2021.

(4) RECARBRIO™

Merck submitted an application for new technology add-on payments for RECARBRIO™ for FY 2021. RECARBRIO™ is a fixed-dose combination of imipenem, a penem antibacterial; cilastatin, a renal dehydropeptidase inhibitor; and relebactam, a novel β-lactamase inhibitor (BLI). According to the applicant, RECARBRIO™ is intended for the treatment of complicated urinary tract infections (cUTI) and complicated intra-abdominal infections (cIAI) for patients 18 years of age and older. RECARBRIO™ is administered via intravenous infusion.

The applicant explained that the recommended dose of RECARBRIO™ is 1.25 grams administered by intravenous infusion over 30 minutes every 6 hours in patients 18 years of age and older with creatinine clearance (CLcr) 90 mL/min or greater. According to the applicant, the recommended treatment course suggests that a patient will receive 1 vial per dose and 4 doses per day. Per RECARBRIO™'s prescribing information, the recommended duration of treatment with RECARBRIO™ is 4 days to 14 days.

According to information provided by the applicant, RECARBRIO™ received FDA approval on July 16, 2019 and is designated by FDA as a Qualified Infectious Disease Product (QIDP). According to the applicant, RECARBRIO™ became commercially available on the U.S. market on January 6, 2020. The applicant stated that the delay in commercial availability was due to manufacturing considerations. According to the applicant, RECARBRIO™ can be identified with ICD–10–PCS codes XW033U5 (Introduction of imipenem-cilastatin-relebactam anti-infective into peripheral vein, percutaneous approach, new technology group 5) or XW043U5 (Introduction of imipenem-cilastatin-relebactam anti-infective into central vein, percutaneous approach, new technology group 5).

To demonstrate that the technology meets the cost criterion, the applicant searched the FY 2018 MedPAR Limited Data Set (LDS) for cases reporting ICD–10–CM diagnosis codes for either cUTI or cIAI with ICD–10–PCS codes XW033U5 (Introduction of imipenem-cilastatin-relebactam anti-infective into peripheral vein, percutaneous approach, new technology group 5 or XW043U5 (Introduction of imipenem-cilastatin-relebactam anti-infective into central vein, percutaneous approach, new technology group 5) to identify the MS–DRGs to which potential cases representing hospitalized patients who may be eligible for treatment involving RECABRIO™ would be mapped. The applicant identified a total 25,379 cases which were mapped to 453 unique MS–DRGs. There were 299 MS–DRGs with minimal frequencies (fewer than 11 cases), with a total of 1,140 cases associated with such low-volume MS–DRGs. After excluding the cases that were mapped to these low-volume MS–DRGs, the applicant identified 24,239 cases that were mapped to 153 unique MS–DRGs. The applicant examined associated charges per MS–DRG and removed all pharmacy charges that will be replaced through the use of RECARBRIO™. The applicant standardized the charges and inflated the charges by applying the FY 2020 IPPS/LTCH PPS final rule outlier charge inflation factor of 1.11100 (84 FR 42629). The applicant estimated an average cost of RECARBRIO™ for the treatment of cUTI or cIAI in the inpatient setting based on the recommended dose of 1.25 grams (imipenem 500 mg, cilastatin 500 mg, relebactam 250 mg) administered by intravenous infusion over 30 minutes every 6 hours in patients 18 years of age and older with creatinine clearance (CLcr) 90 mL/min or greater. As stated above, according to the applicant, the recommended treatment course suggests that a patient will receive 1 vial per dose, 4 doses per day within a recommended treatment duration of 4 to 14 days. To determine the cost per patient, the applicant stated it used the FY 2018 MedPAR analysis of total cases representing hospitalized patients who may be eligible for treatment involving RECARBRIO™ to identify a percentage of total cases per indication: cUTI equaled 88.6 percent of cases and cIAI equaled 11.4 percent. According to the applicant, it next identified the average length of stay per indication: cUTI 6.4 days and cIAI 9.7 days. According to the applicant, it also assumed that 70 percent of patients would receive RECARBRIO™ beginning on the fourth day after admission while the remaining 30 percent of these patients would receive RECARBRIO™ beginning on the second day of their hospitalization. According to the applicant, it multiplied the daily dose cost by the two scenarios for each cUTI and cIAI indication to determine the cost per stay for each indication by days of drug use. According to the applicant, next it multiplied the cost per stay for each indication by the share of cases by days in use (70/30 percent split) to determine the weighted cost for days in use estimation. According to the applicant, it summed the 70/30 percent case breakdown (weighted cost) for patients initiating on day 2 and 4 to determine the average cost per indication for cUTI and cIAI. Finally, according to the applicant, it multiplied the average cost per indication by the percent of total cases for cUTI and cIAI, then summed them to get the overall average cost. The applicant converted this cost to a charge by dividing the costs by the national average cost-to-charge ratio of 0.189 for drugs from the FY 2020 IPPS/LTCH PPS final rule (84 FR 42179) and added the resulting charges to determine the final inflated average case-weighted standardized charge per case. The applicant calculated a final inflated average case-weighted standardized charge per case of $75,122 and an average case-weighted threshold amount of $52,216.

The applicant also calculated an average case-weighted standardized charge per case for cUTI and cIAI separately using the same methodology previously described and determined final inflated average case-weighted standardized charges per case of $70,765 for cUTI and $109,403 for cIAI

and average case-weighted thresholds of $50,210 for cUTI and $67,531 for cIAI. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in each scenario, the applicant maintained that the technology met the cost criterion.

We agree with the applicant that it meets the cost criterion and therefore are proposing to approve RECARBRIO™ for new technology add-on payments for FY 2021. As previously noted, the applicant stated that RECARBRIO™ can be identified by ICD–10–PCS codes XW033U5 (Introduction of imipenem-cilastatin-relebactam anti-infective into peripheral vein, percutaneous approach, new technology group 5) or XW043U5 (Introduction of imipenem-cilastatin-relebactam anti-infective into central vein, percutaneous approach, new technology group 5).

Based on preliminary information from the applicant at the time of this proposed rule, the cost of RECARBRIO™ is $4,710.37 (which is based on the cost per patient determined using the methodology as previously described in the analysis of the cost criterion). We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under 412.88(a)(2), we limit new technology add-on payments for QIDPs to 75 percent of the costs of the new medical service or technology, or 75 percent of the amount by which the costs of the case exceed the MS–DRG payment. As a result, we are proposing that the maximum new technology add-on payment for a case involving RECARBRIO™ would be $3,532.78 for FY 2021 (that is 75 percent of the average cost of the technology).

We are inviting public comments on whether RECARBRIO™ meets the cost criterion and our proposal to approve new technology add-on payments for the RECARBRIO™ for FY 2021.

(5) XENLETA

Nabriva Therapeutics submitted an application for XENLETA, a pleuromutilin antibacterial agent representing the first intravenous (IV) and oral treatment option from a novel class of antibiotics for community-acquired bacterial pneumonia (CABP). XENLETA is indicated for the treatment of adults with CABP caused by the following susceptible microorganisms: *Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible isolates), Haemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae, and Chlamydophila pneumoniae.* Per the applicant, XENLETA also has in vitro activity against methicillin resistant *Staphylococcus aureus.*

Per the applicant, pleuromutilins inhibit bacterial protein synthesis by binding to the A- and P-sites of the peptidyl transferase center (PTC) in the large ribosomal subunit of the bacterial ribosome. The applicant asserts that this unique binding site in the highly conserved core of the ribosomal PTC is specific to pleuromutilins, and it confers a lack of cross-resistance with other classes, as well as a low propensity for developing bacterial resistance.

The applicant noted that there are two methods of administering XENLETA. As a tablet containing 600 mg of XENLETA, it is administered orally every 12 hours for a duration of 5 days. As an injection, XENLETA contains 150 mg of the drug and is administered every 12 hours by IV infusion over 60 minutes for a duration of 5 to 7 days, with the option to switch to XENLETA tablets administered every 12 hours to complete the treatment course.

With respect to the newness criterion, the applicant indicated that XENLETA was approved by the FDA under the Qualified Infectious Disease Product (QIDP) designation, and granted fast-track designation. XENLETA received FDA approval on August 19, 2019 for a new drug application indicated for the oral and IV formulations of XENLETA for the treatment of CABP in adults. The applicant indicated that XENLETA was commercially available on the U.S. market on September 10, 2019 and the slight delay from approval to availability was due to the shipment of drug to the distribution channels.

There are currently no ICD–10–PCS procedure codes that uniquely identify the use of the XENLETA. We note the applicant submitted a request for approval for a unique ICD–10–PCS procedure code to uniquely identify use of the technology beginning in FY 2021.

With respect to the cost criterion, the applicant presented three scenarios varying in the assumptions regarding the form of XENLETA used to treat the patient and the duration of treatment. For the first analysis, the applicant assumed that a patient population with CABP received 7 days of IV treatment with XENLETA. For the second analysis, the applicant assumed the patient population received 3.2 days of IV treatment with XENLETA before switching to oral XENLETA for 3.8 days. For the third analysis, the applicant assumed the patient population received oral XENLETA for 5 days. The applicant explained that patients receiving XENLETA in the inpatient hospital setting would receive it through IV treatment. However, some patients may be switched to oral form during care, which was observed for some patients in clinical trial. While the applicant does not expect many patients to be treated with only oral XENLETA in the inpatient setting, they conducted a sensitivity analysis based on 5 days of treatment with oral XENLETA, as oral treatment is possible in hospital.

Across all three analyses, the applicant first searched the FY 2018 MedPAR Final Rule Limited Data Set for potential cases representing patients diagnosed with CABP and eligible for treatment with XENLETA. The applicant limited the cohort to cases that had an indication on the claim that the pneumonia was present on admission. The applicant searched for claims that had one of the following ICD–10–CM diagnosis codes as a principal or secondary diagnosis:

ICD-10-CM Diagnosis Code	Description
A48.1	Legionnaires disease
J13	Pneumonia due to Streptococcus pneumoniae
J14	Pneumonia due to Haemophilus influenzae
J15.20	Pneumonia due to staphylococcus, unspecified
J15.211	Pneumonia due to methicillin susceptible Staphylococcus aureus
J15.7	Pneumonia due to Mycoplasma pneumoniae
J15.8	Pneumonia due to other specified bacteria
J15.9	Unspecified bacterial pneumonia
J16.0	Chlamydial pneumonia
J16.8	Pneumonia due to other specified infectious organisms
J17	Pneumonia in diseases classified elsewhere
J18.0	Bronchopneumonia, unspecified organism
J18.1	Lobar pneumonia, unspecified organism
J18.2	Hypostatic pneumonia, unspecified organism
J18.8	Other pneumonia, unspecified organism
J18.9	Pneumonia, unspecified organism

The applicant identified 1,225,713 cases from the FY 2018 MedPAR LDS file spanning 357 MS–DRGs. The applicant then excluded cases that mapped to MS–DRGs with a volume of 10 cases or fewer, resulting in a total of 1,225,561 cases spanning 319 unique MS–DRGs. The applicant considered these cases to be the primary cohort of the cost analysis. The applicant noted that the most common MS–DRGs in the cohort are 871, 193, 194, 291, and 190, which account for 61 percent of cases. The applicant presented the following table of the top 20 MS–DRGs in the primary cohort with more than 10 cases:

MS-DRG	Description
064	Intracranial Hemorrhage or Cerebral Infarction with MCC
175	Pulmonary Embolism with MCC
177	Respiratory Infections and Inflammations with MCC
180	Respiratory Neoplasms with MCC
189	Pulmonary Edema and Respiratory Failure
190	Chronic Obstructive Pulmonary Disease with MCC
193	Simple Pneumonia and Pleurisy with MCC
194	Simple Pneumonia and Pleurisy with CC
195	Simple Pneumonia and Pleurisy without CC/MCC
207	Respiratory System Diagnosis with Ventilator Support >96 hours
208	Respiratory System Diagnosis with Ventilator Support <=96 hours
280	Acute Myocardial Infarction, Discharged Alive with MCC
291	Heart Failure and Shock with MCC
308	Cardiac Arrhythmia and Conduction Disorders with MCC
377	G.I. Hemorrhage with MCC
682	Renal Failure with MCC
689	Kidney and Urinary Tract Infections with MCC
853	Infectious and Parasitic Diseases with O.R. Procedure with MCC
870	Septicemia or Severe Sepsis with MV >96 hours
871	Septicemia or Severe Sepsis without MV >96 hours with MCC

For all three scenarios, the applicant calculated an average case-weighted unstandardized charge per case of $73,911. The applicant then removed charges for the prior technology being replaced, which included the average charge associated with the cost of antibiotics that are the current standard of care. The applicant varied assumptions by scenario to reflect appropriate substitute treatments for the different forms of XENLETA, as noted previously. For each scenario, the applicant calculated the cost of therapy for each standard of care drug using dosing information, the duration of treatment, and wholesale acquisition costs and converted them to charges using the national pharmacy cost-to-charge ratio published in the FY 2020 IPPS final rule (84 FR 42179). After adjusting for prior technology, the applicant standardized the charges and applied an inflation factor of 11.1 percent, which is the 2-year inflation factor used by CMS to calculate outlier threshold charges in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42629), to update the charges from FY 2018 to FY 2020. The applicant added charges for the new technology, which it again calculated using the national pharmacy cost-to-charge ratio.

For all three scenarios, the applicant conducted a sensitivity analysis testing alternative assumptions regarding the charges associated with prior technology that could be replaced by XENLETA. The applicant acknowledged that it is possible for some patients with CABP to receive more than one antibiotic. The applicant examined the cost criterion for each scenario after doubling the charges associated with prior technology to account for multiple antibiotics. Furthermore, the applicant tested alterative assumptions regarding the MS–DRGs that cases representing patients eligible for treatment with XENLETA mapped. Specifically, the applicant examined the cost criterion for the top 10 MS–DRGs, the top 20 MS–DRGs, and the top MS–DRGs that accounted for 75 percent of cases.

Across all three scenarios and the sensitivity analyses testing alternative assumptions, the applicant determined that the final inflated average standardized charge per case exceeded the case-weighted threshold, with the difference ranging from $4,547 to $17,907. The following table summarizes the results of the applicant's cost analyses. The applicant maintained that XENLETA meets the cost criterion.

		Case-Weighted Threshold	Final Inflated Average Case-Weighted Standardized Charge Per Case	Difference
Scenario 1 (Patient with CABP treated with 7 days of IV XENLETA)	**100 percent of cases**	$61,896	$75,459	$13,563
	Top 10 MS-DRGs	$51,730	$56,277	$4,547
	Top 25 MS-DRGs	$54,859	$60,989	$6,130
	75 percent of cases	$53,908	$59,336	$5,428
Scenario 2 (Patient with CABP treated with Blend of IV and Oral XENLETA)	**100 percent of cases**	$61,896	$77,030	$15,134
	Top 10 MS-DRGs	$51,730	$57,849	$6,119
	Top 25 MS-DRGs	$54,859	$62,560	$7,707
	75 percent of cases	$53,908	$60,908	$7,000
Scenario 3 (Patient with CABP treated with oral XENLETA for 5 days)	**100 percent of cases**	$61,896	$78,803	$17,907
	Top 10 MS-DRGs	$51,730	$60,642	$8,912
	Top 25 MS-DRGs	$54,859	$65,349	$10,490
	75 percent of cases	$53,908	$63,698	$9,790

We agree with the applicant that XENLETA meets the cost criterion and therefore are proposing to approve XENLETA for new technology add-on payments for FY 2021. As previously noted, the applicant has submitted a request for approval for a new ICD–10–PCS procedure code to uniquely identify cases involving the use of XENLETA. We anticipate additional coding information will be available for the final rule.

Based on preliminary information from the applicant at the time of this proposed rule, the cost of XENLETA is $1,701. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments for QIDPs to 75 percent of the costs of the new medical service or technology, or 75 percent of the amount by which the costs of the case exceed the MS–DRG payment. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of XENLETA would be $1,275.75 for FY 2021 (that is 75 percent of the average cost of the technology).

We are inviting public comments on whether XENLETA meets the cost criterion and our proposal to approve new technology add-on payments for XENLETA for FY 2021.

(6) ZERBAXA®

Merck submitted an application for new technology add-on payments for ZERBAXA® for FY 2021. ZERBAXA® (ceftolozane and tazobactam) is a combination of ceftolozane, a cephalosporin antibacterial, and tazobactam, a β-lactamase inhibitor (BLI), indicated in patients 18 years or older for the treatment of the following infections caused by designated susceptible microorganisms:

- Complicated Intra-abdominal Infections (cIAI), used in combination with metronidazole;
- Complicated Urinary Tract Infections (cUTI), Including Pyelonephriti;
- Hospital-acquired Bacterial Pneumonia and Ventilator-associated Bacterial Pneumonia (HABP/VABP).

According to the applicant, the FDA initially approved ZERBAXA® on December 19, 2014 for the treatment of complicated intra-abdominal infections (cIAI) and for complicated urinary tract infections (cUTI) under a New Drug Application (NDA). ZERBAXA® was then approved on June 3, 2019 for the indication of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP), also under a NDA. The applicant noted that ZERBAXA® was designated as a Quality Infectious Disease Product (QIDP) as well as provided Fast Track and Priority Review consideration by the FDA. The applicant also indicated that ZERBAXA® was commercially available on the U.S. market upon FDA approval. We believe only the indication approved in 2019 for treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) is eligible for new technology add on payments for FY 2021 because the first indication was approved in 2014 and is therefore beyond the 3-year newness period.

The applicant noted that there are currently no ICD–10–PCS procedure codes that could be used to uniquely identify the use of ZERBAXA®. However, we note that the applicant has submitted a request for approval for a new ICD–10–PCS procedure code to uniquely identify ZERBAXA® administration effective for FY 2021.

According to the applicant, to reduce the development of drug-resistant bacteria and maintain the effectiveness of ZERBAXA® and other antibacterial drugs, ZERBAXA® should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. According to the applicant, when culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

The applicant explained that the recommended dosage of ZERBAXA® for injection when used for HABP/VABP is 3 g (ceftolozane 2 g and tazobactam 1 g) administered every 8 hours by intravenous infusion over 1 hour in patients 18 years or older and with a creatinine clearance (CrCl) greater than 50 mL/min. The duration of therapy should be guided by the severity and site of infection and the patient's clinical and bacteriological progress. Dose adjustment is required for patients with CrCl 50 mL/min or less. All doses of ZERBAXA® are administered over 1 hour. For patients with changing renal function, CrCl is monitored at least daily and dosage of ZERBAXA® adjusted accordingly.

With regard to the cost criterion, the applicant used the FY 2018 MedPAR Limited Data Set (LDS) to identify the MS–DRGs to which potential cases representing hospitalized patients who may be eligible for treatment involving

ZERBAXA® would be mapped. According to the applicant, ZERBAXA® is indicated for the treatment of hospitalized patients who have been diagnosed with cUTI, cIAI, VABP, or HABP conditions. The applicant conducted multiple analyses based on ICD–10–CM diagnosis codes for various scenarios involving patients diagnosed with cUTI, cIAI, VABP, or HABP. The applicant stated that cases representing patients who may be eligible to receive treatment through the administration of ZERBAXA® are identified with ICD–10–PCS codes 3E03329 (Introduction of other anti-infective into peripheral vein, percutaneous approach) or 3E04329 (Introduction of other anti-infective into central vein, percutaneous approach). For the purposes of analyzing the cost criterion for this technology for new technology add-on payment for FY 2021, we are only discussing the applicant's cost analysis related to the HABP and VABP indications because, as we noted previously, the first indications (cUTI, cIAI) were approved in 2014 and are therefore beyond the 3-year newness period. For the HABP and VABP scenarios, the applicant submitted the following three cost analysis scenarios: Cases with a HABP diagnosis only, cases with a VABP diagnosis only and cases with either a HABP or VABP diagnosis. For all three scenarios, the applicant calculated the average charges per case for each MS–DRG without standardizing the charges. Next, the applicant removed 100 percent of the drug charges from the relevant cases to conservatively estimate the charges for drugs that potentially may be replaced by or avoided through use of ZERBAXA®. After removing these drug charges from unstandardized average charge amounts, the applicant calculated the average standardized charge per case for each MS—DRG. Then, the applicant inflated the standardized average charges by 11.1 percent, which is the 2-year inflation factor used by CMS to calculate outlier threshold charges in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42629), to update the charges from FY 2018 to FY 2020. The applicant added charges for the new technology, which it again calculated using the national pharmacy cost-to-charge ratio. Finally, the applicant calculated the final inflated average case-weighted standardized charge per case as well as the case-weighted threshold amount. The following table summarizes the results of the applicant's cost analyses. The applicant maintained that ZERBAXA® meets the cost criterion.

Scenario	Cases	Case-Weighted Threshold	Final Inflated Average Case-Weighted Standardized Charge Per Case	Difference
Cases with VABP	6,880	$203,394	$306,882	$103,488
Cases with HABP	121,748	$114,725	$188,193	$73,468
Cases with Either VABP or HABP	124,402	$115,090	$187,293	$72,203

We agree with the applicant that ZERBAXA® meets the cost criterion and therefore are proposing to approve ZERBAXA® for new technology add-on payments for FY 2021. As previously noted, the applicant has submitted a request for approval for a new ICD–10–PCS procedure code to uniquely identify cases involving the use of ZERBAXA®. We anticipate additional coding information will be available for the final rule.

Based on preliminary information from the applicant at the time of this proposed rule, the cost of ZERBAXA® is $2,449.31. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments for QIDPs to 75 percent of the costs of the new medical service or technology, or 75 percent of the amount by which the costs of the case exceed the MS–DRG payment. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of ZERBAXA® would be $1,836.98 for FY 2021 (that is 75 percent of the average cost of the technology).

We are inviting public comments on whether ZERBAXA® meets the cost criterion and our proposal to approve new technology add-on payments for ZERBAXA® for FY 2021.

7. Technical Revision to the New Technology Add-On Payment Regulations at 42 CFR 412.88

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42297 through 42300, and 42612), we finalized an increase in the new technology add-on payment percentage. Specifically, for a new technology other than a medical product designated by FDA as a QIDP, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 65 percent of the costs of the new medical service or technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment. We also finalized a separate increase in the new technology add-on payment percentage to 75 percent for a new technology that is a medical product designated by FDA as a QIDP. Under this finalized policy, unless the discharge qualifies for an outlier payment, the additional Medicare payment will be limited to the full MS–DRG payment plus 65 percent (or 75 percent for a medical product designated by FDA as a QIDP) of the estimated costs of the new technology or medical service. We also finalized revisions to paragraphs (a)(2) and (b) under § 412.88 to reflect these changes to the calculation of the new technology add-on payment amount beginning in FY 2020, including the finalized percentage for a medical product designated by FDA as a QIDP. Specifically, the new technology add-on payment percentage of 65 percent for a new technology other than a medical product designated by FDA as a QIDP is set forth in § 412.88(a)(2)(ii)(A). The

new technology add-on payment percentage of 75 percent for a medical product designated by FDA as a QIDP is set forth at § 412.88(a)(2)(ii)(B). However, in our revision to paragraph (a)(2)(ii), in setting forth the new technology add-on payment amounts for discharges occurring on or after October 1, 2019, we made an inadvertent error when referencing the separate new technology add-on payment percentage for QIDPs under § 412.88(a)(2)(ii)(B). Specifically, in referencing the add-on percentage for QIDPs, § 412.88(a)(2)(ii)(A) refers to ''paragraph (a)(2)(ii)(*2*) of this section'' when the correct citation should be ''paragraph (a)(2)(ii)(B) of this section''. We are proposing to revise § 412.88(a)(2)(ii)(A) to correct this technical error.

8. Technical Clarification to the Alternative Pathway for Certain Transformative New Devices

As described previously, in the FY 2020 IPPS/LTCH PPS final rule, we finalized an alternative pathway for new technology add-on payments for certain transformative new devices. Under the existing regulations at § 412.87(c), to be eligible for approval under this alternative pathway, the device must be part of the FDA's Breakthrough Devices Program and have received FDA marketing authorization.

We have received questions from the public regarding CMS's intent with respect to the ''marketing authorization'' required for purposes of approval under the alternative pathway for certain transformative new devices at § 412.87(c). Some of the public appear to assert that so long as a technology has received marketing authorization for any indication, even if that indication differs from the indication for which the technology was designated by FDA as part of the Breakthrough Devices Program, the technology would meet the marketing authorization requirement at § 412.87(c). For example, consider a device that received FDA marketing authorization in 2019 for use in the heart. The same device is then designated by the FDA as part of the Breakthrough Devices Program for use in the liver in 2020, but has not yet received marketing authorization for indicated use in the liver. Some of the public have asserted that in such a scenario, the original marketing authorization for use in the heart could be used with FDA's Breakthrough Device indication for use in the liver to qualify under the alternative pathway for certain transformative new devices and receive new technology add-on payments for use in the liver in FY 2021. Because of this potential confusion, we are clarifying that, consistent with our existing policies for determining newness where a product has more than one indication, an applicant cannot combine a marketing authorization for an indication that differs from the technology's indication under the Breakthrough Device Program, and for which the applicant is seeking to qualify for the new technology add-on payment, for purposes of approval under the alternative pathway for certain transformative devices.

Section 1886(d)(5)(K)(ii)(II) of the Act provides for the collection of data with respect to the costs of a new medical service or technology described in subclause (I) for a period of not less than 2 years and not more than 3 years beginning on the date on which an inpatient hospital code is issued with respect to the service or technology. As explained in the FY 2005 IPPS final rule (69 FR 49002), the intent of section 1886(d)(5)(K) of the Act and regulations under § 412.87(b)(2) is to pay for new medical services and technologies for the first 2 to 3 years that a product comes on the market, during the period when the costs of the new technology are not yet fully reflected in the DRG weights. Generally, we use the FDA approval (*i.e.,* marketing authorization) as the indicator of the time when a technology begins to become available on the market and data reflecting the costs of the technology begin to become available for recalibration of the DRGs. In some specific circumstances, we have recognized a date later than the FDA approval as the appropriate starting point for the 2-year to 3-year period. The costs of the new medical service or technology, once paid for by Medicare for this 2-year to 3-year period, are accounted for in the MedPAR data that are used to recalibrate the DRG weights on an annual basis. Therefore, we limit the add-on payment window for those technologies that have passed this 2- to 3-year timeframe. In the September 7, 2001 final rule that established the new technology add-on payment regulations (66 FR 46915), we also indicated that an existing technology can receive new technology add on payments for a new use or indication. While we recognize that a technology can have multiple indications, each indication has its own newness period and must meet the new technology add on payment criteria. The applicable criteria will depend on whether the technology is eligible for an alternative new technology add-on payment pathway. However, each indication for the technology is evaluated separately from any other indication, including with respect to the start of the newness period, to determine whether the technology is eligible for new technology add-on payments when used for that indication.

Based on this policy, using the previous example, the newness period for the heart indication began in 2019 when the technology received marketing authorization from FDA for that indication, while the newness period for the liver indication would begin when the device receives marketing authorization specifically indicated for the liver. These are two distinct newness periods. Consistent with this policy, the newness period that began with the original marketing authorization for indicated use in the heart cannot be combined with FDA's Breakthrough Device indication for use in the liver for purposes of the marketing authorization required for approval under the alternative pathway to receive new technology add-on payments in FY 2021.

To address this potential confusion, we are clarifying our policy that a new medical device under this alternative pathway must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation and making a conforming change to the regulations at § 412.87(c)(1). Specifically, with regard to the eligibility criteria for approval under the alternative pathway for certain transformative new devices, we are proposing to amend the regulations in § 412.87(c)(1) to state that ''A new medical device is part of the FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.'' We note that we are also proposing to make similar amendments to the regulations at § 412.87(d) for the alternative pathway for certain antimicrobial products, as discussed in section II.G.9.b. of this preamble of this proposed rule.

9. Proposed Revisions to New Technology Add-On Payments for Certain Antimicrobial Products

a. Background

In the FY 2020 IPPS/LTCH PPS final rule, after consideration of public comments, we finalized changes to the new technology add-on payment policy related to certain antimicrobial products. These changes were finalized in recognition of the significant concerns related to antimicrobial resistance and its serious impact on Medicare beneficiaries and public health overall, and consistent with the Administration's commitment to

address issues related to antimicrobial resistance, in order to help secure access to antibiotics, and improve health outcomes for Medicare beneficiaries in a manner that is as expeditious as possible. Firstly, as described earlier in this section, we finalized an alternative new technology add-on payment pathway for a product that is designated by FDA as a Qualified Infectious Disease Product (QIDP). Under this alternative pathway, at existing § 412.87(d), for applications received for new technology add-on payments for FY 2021 and subsequent fiscal years, if a technology receives FDA's QIDP designation and received FDA marketing authorization, it will be considered new and not substantially similar to an existing technology for purposes of new technology add-on payments and will not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Under this pathway, a medical product that has received FDA marketing authorization and is designated by the FDA as a QIDP will need to meet the cost criterion under § 412.87(b)(3), as reflected in § 412.87(d)(3) (84 FR 42292 through 42297).

In addition, beginning with FY 2020, we adopted a general increase in the maximum new technology add-on payment amount from 50 percent to 65 percent; however, we adopted a higher increase to 75 percent for a product that is designated by FDA as a QIDP. Therefore, under existing § 412.88(a)(2)(ii)(B), for a new technology that is a medical product designated by FDA as a QIDP, the new technology add-on payment is equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment (84 FR 42297 through 42300).

We stated that we believe Medicare beneficiaries may be disproportionately impacted by antimicrobial resistance, due in large part to the elderly's unique vulnerability to drug-resistant infections (for example, due to age-related and/or disease-related immunosuppression and greater pathogen exposure via catheter use). As such, antimicrobial resistance results in a substantial number of additional hospital days for Medicare beneficiaries, resulting in significant unnecessary health care expenditures. In November 2019, the CDC released its updated ''Antibiotic Resistance Threats in the United States'' (AR Threats Report) [459] indicating that antibiotic-resistant bacteria and fungi cause more than 2.8 million infections and 35,000 deaths in the United States each year. This report also shows that there were nearly twice as many annual deaths from antibiotic resistance as CDC originally reported in 2013, and underscores the continued threat of antibiotic resistance in the U.S. This recent information highlights the significant concerns and impacts related to antimicrobial resistance and emphasizes the continued importance of this issue both with respect to Medicare beneficiaries and public health overall. In this section, we discuss our proposals for FY 2021 regarding new technology add-on payments and certain antimicrobials, including QIDPs.

b. Proposed Changes and Technical Clarification to the Alternative Pathway for Certain Antimicrobial Products

As described previously, in the FY 2020 IPPS/LTCH PPS final rule, we finalized an alternative pathway for new technology add-on payments for certain antimicrobial products. Under the existing regulations at § 412.87(d), to be eligible for approval under this alternative pathway, the antimicrobial product must be designated by the FDA as a QIDP and have received FDA marketing authorization. Under this alternative pathway, such a QIDP will be considered new and not substantially similar to an existing technology for purposes of new technology add-on payments and will not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

The FDA also has the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD pathway), which encourages the development of safe and effective drug products that address unmet needs of patients with serious bacterial and fungal infections.[460] [461] Specifically, an antibacterial or antifungal drug approved under the LPAD pathway is used to treat a serious or life-threatening infection in a limited population of patients with unmet needs. We believe that in order to address the continued issues related to antimicrobial resistance discussed previously, as well as further help to support access to antibiotics and improve health outcomes for Medicare beneficiaries, it is appropriate to expand our policy for an alternative new technology add-on payment pathway for a product that is designated by the FDA as a QIDP to include products approved as a LPAD as well. Therefore, we are proposing to expand our current alternative new technology add-on payment pathway for QIDPs to include products approved under the LPAD pathway as well to further address the continued issues related to antimicrobial resistance discussed previously. Under this proposed policy, for applications received for new technology add-on payments for FY 2022 and subsequent fiscal years, if an antimicrobial drug is approved by FDA under the LPAD pathway it will be considered new and not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Under this proposal, an antimicrobial product that is approved by FDA under the LPAD pathway will need to meet the cost criterion under § 412.87(b)(3).

We are proposing to revise § 412.87(d)(1) to reflect this proposal, by adding drugs approved under FDA's LPAD pathway to the current alternative new technology add-on payment pathway for QIDPs at proposed new § 412.87(d)(1)(ii), beginning with discharges occurring on or after October 1, 2021. We are also proposing to revise the title of existing § 412.87(d) to refer more broadly to ''certain antimicrobial products'' rather than specifying in this title the particular FDA programs for antimicrobial products (that is, QIDPs and LPADs) that are the subject of this alternative new technology add-on payment pathway.

We note, FDA may approve a drug under the LPAD pathway if it meets certain statutory standards for approval, as applicable, including that FDA receives a written request from the sponsor to approve the drug as a limited population drug. Sponsors seeking approval of a drug under the LPAD pathway are not precluded from seeking designation or approval under any other applicable provision for which the drug otherwise qualifies (for example, fast track designation, breakthrough therapy designation, regenerative medicine advanced therapy designation, accelerated approval, priority review designation). A sponsor who seeks approval of a drug under the LPAD pathway may also seek designation, as applicable, for other programs,

[459] *https://www.cdc.gov/drugresistance/biggest-threats.html.*

[460] Section 506(h) of the FD&C Act, 21 U.S.C. 356(h).

[461] *https://www.fda.gov/media/113729/download.*

including QIDP or orphan drug designation. Although FDA may provide advice on potential eligibility, FDA intends to make the determination of whether a drug meets the criteria for the LPAD pathway at the time of the drug's approval. (For additional information, see *https://www.fda.gov/media/113729/download*.)

As such, an applicant that has not received FDA approval and which has requested approval under the LPAD pathway may not know with certainty at the time it applies for new technology add on payments under the proposed expanded alternative pathway for certain antimicrobial products whether it will qualify for approval under that pathway. As noted previously in section II.G.1.c. of the preamble of this proposed rule, CMS will review the application based on the information provided by the applicant under the alternative pathway specified by the applicant. If the applicant drug ultimately does not receive approval under the LPAD pathway (but receives FDA approval otherwise) and is not designated as a QIDP, the technology would not be eligible for the alternative pathway for certain antimicrobial products and the applicant would need to re-apply for new technology add on payments under the traditional pathway at § 412.87(b) for the following fiscal year in order to seek approval for new technology add on payments.

We are also proposing to increase the maximum new technology add-on payment percentage for a product approved under FDA's LPAD pathway, from 65 percent to 75 percent, consistent with the new technology add on payment percentage that currently applies for a product that is designated by FDA as a QIDP. As previously noted, an antibacterial or antifungal drug approved under the LPAD pathway is used to treat a serious or life-threatening infection in a limited population of patients with unmet needs, and therefore we believe increasing the add-on payment amount for these products would further the goal of helping secure access to antibiotics and improving health outcomes for Medicare beneficiaries to address the continued significant concerns related to antimicrobial resistance as discussed previously. Therefore, we are proposing to revise § 412.88(a)(2)(ii)(B) and (b)(2) by adding products approved under FDA's LPAD pathway, beginning with discharges occurring on or after October 1, 2020.

In addition to adding drugs approved under the FDA's LPAD pathway to the alternative new technology add-on payment pathway for certain antimicrobial products, we are clarifying our policy regarding marketing authorization for QIDPs. As discussed previously, we have received questions from the public regarding the ''marketing authorization'' required for purposes of approval under the alternative pathway for certain transformative new devices, and are therefore clarifying our policy regarding the marketing authorization requirement under this pathway and proposing conforming amendments to the regulations at § 412.87(c)(1). We refer the reader to the previous discussion in section II.G.8. of this preamble of this proposed rule for complete details regarding this clarification.

The current regulations at § 412.87(d)(1) regarding the alternative pathway for new technology add-on payments for certain antimicrobial products also require marketing authorization for a QIDP to be eligible for approval under this pathway. Therefore, similar to the clarification regarding the transformative new devices alternative pathway, we are clarifying that a new medical product seeking approval for the new technology add-on payment under the alternative pathway for QIDPs must receive marketing authorization for the indication covered by the QIDP designation. We are proposing to amend the regulations at § 412.87(d)(1) describing the alternative pathway for QIDPs (which, as amended, would appear at § 412.87(d)(1)(i)) to state that ''A new medical product is designated by the FDA as a Qualified Infectious Disease Product and has received marketing authorization for the indication covered by the Qualified Infectious Disease Product designation.''

c. Proposed Change to Announcement of Determinations and Deadline for Consideration of New Medical Service or Technology Applications for Certain Antimicrobial Products

As noted previously, in the FY 2009 IPPS final rule (73 FR 48562), we amended § 412.87(c) (now § 412.87(e) of the existing regulations) to specify that all applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. We stated that this deadline would provide us with enough time to fully consider all of the new medical service or technology add-on payment criteria for each application and maintain predictability in the IPPS for the coming fiscal year. We also stated and further explained that we believe that July 1 of each year provides an appropriate balance between the necessity for adequate time to fully evaluate the applications, the requirement to publish the IPPS final rule by August 1 of each year, and the commenters' concerns that potential new technology applicants have some flexibility with respect to when their technology receives FDA approval or clearance.

We continue to believe that our policy of requiring FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered appropriately balances the length of time required to fully consider all of the new medical service or technology add-on payment criteria for each application while also providing flexibility to potential new technology add-on payment applicants. At the same time, we also believe the significant ongoing concerns regarding antimicrobial resistance, and the need to help secure access to antibiotics for Medicare beneficiaries in a manner that is as expeditious as possible, may warrant additional flexibility with respect to applications for new technology add-on payments for certain antimicrobial products. Further, we note that under the new alternative pathway for certain antimicrobial products, upon FDA marketing authorization, such products are considered new and not substantially similar to an existing technology and do not need to demonstrate substantial clinical improvement, resulting in a difference in the amount of information and time required for CMS to complete its evaluation as compared to technologies for which it must fully consider of all of the new medical service or technology add-on payment criteria. For these reasons, and for the reasons stated previously regarding the significant ongoing concerns related to the public health crisis represented by antimicrobial resistance, consistent with the Administration's commitment to address issues related to antimicrobial resistance, and to continue to help secure access to antibiotics and improve health outcomes for Medicare beneficiaries in a manner that is as expeditious as possible, we are proposing a process by which a technology that meets the new technology add-on payment criteria under the alternative pathway for products designated as QIDPs or, as proposed previously, approved under FDA's LPAD pathway, would receive conditional approval for such payment even if the product has not been granted FDA marketing authorization by July 1

(the existing deadline by which any technology must be granted FDA marketing authorization in order to be eligible for a new technology add-on payment). (We note that for the remainder of this discussion, we refer to the alternative pathway at § 412.87(d), which we are proposing would also include products approved under the LPAD pathway beginning with applications submitted for new technology add-on payments for FY 2022, as the ''alternative pathway for certain antimicrobial products'').

Under our proposal, a technology eligible for the new technology add-on payment alternative pathway for certain antimicrobial products would begin receiving the new technology add-on payment effective for discharges the quarter after FDA marketing authorization is granted. We are proposing that the cutoff or deadline for this conditional approval would be FDA marketing authorization by July 1 of the fiscal year for which the applicant is applying for new technology add-on payments. We would consider July 1 to be the cutoff for conditional approval because under this proposal, if the FDA marketing authorization is received on or after July 1, the new technology add-on payment would not be effective for discharges until the beginning of the next quarter on October 1, which would be the start of the next fiscal year. For example, an eligible antimicrobial product is conditionally approved for the new technology add-on payment in the FY 2021 IPPS final rule. However, FDA marketing authorization is not granted until February 1, 2021. The new technology add-on payment for such an antimicrobial product would be made for discharges that use the technology on or after April 1, 2021 (the beginning of the quarter after the FDA marketing authorization was granted). Using the same example, if the eligible antimicrobial product received FDA marketing authorization on or after July 1, 2021, no new technology add-on payments would be made for FY 2021, because the beginning of the next quarter would be October 1, which is the beginning of FY 2022, the next fiscal year. As we discuss further, to be eligible for new technology add-on payments for FY 2022, the applicant would have needed to re-apply for such payments for FY 2022 by the applicable deadline.

In the FY 2009 IPPS final rule (73 FR 48562), we also stated that applications that receive FDA approval of the medical service or technology after July 1 would be able to reapply for the new medical service or technology add-on payment the following year (at which time they would be given full consideration in both the IPPS proposed and final rules). Consistent with this policy, an applicant for an eligible antimicrobial product that does not receive FDA marketing authorization during the conditional approval period described previously would need to evaluate whether it believes it is necessary to re-apply for new technology add-on payments for the following fiscal year. For example, an applicant for an eligible antimicrobial product for FY 2021 that receives conditional approval for FY 2021 (with a conditional approval period of on or after July 1, 2020 and before July 1, 2021) would still need to submit an application for FY 2022 in order to be eligible for new technology add-on payments in FY 2022. The applicant would need to evaluate whether it believes it is necessary to re-apply for new technology add-on payments for the next fiscal year based on when the applicant anticipates receiving FDA marketing authorization. However, we would encourage eligible antimicrobial product applicants to reapply for new technology add-on payments for the next fiscal year in case they do not receive FDA marketing authorization prior to July 1 of the fiscal year for which they initially applied. We also note, as discussed previously, although FDA may provide advice on potential eligibility, FDA intends to make the determination of whether a drug meets the criteria for the LPAD pathway at the time of the drug's approval. As such, an applicant may not know with certainty at the time it applies for new technology add on payments under the alternative pathway for certain antimicrobial products whether it qualifies for that pathway. If the applicant drug ultimately does not receive approval under the LPAD pathway (but receives FDA approval otherwise) and is not designated as a QIDP, the applicant would not be eligible for approval under the alternative pathway for certain antimicrobial products, and therefore, even if the product received conditional approval under this proposal, no new technology add-on payments would be made for that fiscal year. As described previously, the applicant would need to re-apply for new technology add on payments under the traditional pathway at § 412.87(b) for the following fiscal year if the applicant wishes to continue to seek approval for new technology add-on payments.

We are proposing to revise § 412.87(e) to reflect this proposal by adding a new paragraph (3) which would provide for conditional approval for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products at § 412.87(d) that does not receive FDA marketing authorization by the July 1 deadline specified in § 412.87(e)(2), provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments. We are also proposing related revisions to the paragraph (e) introductory text and to paragraph (e)(2) to reflect this proposed new policy.

In addition, we are proposing to make technical clarifications to the regulations in paragraph (e)(2) of § 412.87 by replacing the words ''FDA approval or clearance'' with ''FDA marketing authorization'' which conforms to the existing regulations in paragraphs (c)(1) and (d)(1) of § 412.87. We believe this more precisely describes the current policy and does not change or modify the policy set forth in existing § 412.87(e)(2). For example, under our current policy, in evaluating whether a technology is eligible for new technology add-on payment for a given fiscal year, we consider whether the technology has received marketing authorization by July 1, which could be any of the following: Premarket Approval (PMA); 510(k) clearance; the granting of a De Novo classification request; or approval of a New Drug Application (NDA). Therefore, we believe the term ''marketing authorization'' would more precisely describe the various types of potential FDA approvals, clearances and classifications that we currently consider under our new technology add-on payment policy.

III. Changes to the Hospital Wage Index for Acute Care Hospitals

A. Background

1. Legislative Authority

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. We currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A discussion of the proposed FY 2021 hospital wage index based on the statistical areas appears under section

III.A.2. of the preamble of this proposed rule.

Section 1886(d)(3)(E) of the Act requires the Secretary to update the wage index annually and to base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. (CMS collects these data on the Medicare cost report, CMS Form 2552–10, Worksheet S–3, Parts II, III, and IV. The OMB control number for approved collection of this information is 0938–0050, which expires on March 31, 2022.) This provision also requires that any updates or adjustments to the wage index be made in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. The proposed adjustment for FY 2021 is discussed in section II.B. of the Addendum to this proposed rule.

As discussed in section III.I. of the preamble of this proposed rule, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating IPPS payment amounts. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B), 1886(d)(8)(C), and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The proposed budget neutrality adjustment for FY 2021 is discussed in section II.A.4.b. of the Addendum to this proposed rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. A discussion of the occupational mix adjustment that we are proposing to apply to the FY 2021 wage index appears under sections III.E.3. and F. of the preamble of this proposed rule.

2. Proposed Core-Based Statistical Areas (CBSAs) for the FY 2021 Hospital Wage Index

a. General

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs). The current statistical areas (which were implemented beginning with FY 2015) 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 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963 and 49973 through 49982)) for a full discussion of our implementation of the OMB statistical area delineations beginning with the FY 2015 wage index.

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. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provided 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. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913), we adopted the updates set forth in OMB Bulletin No. 15–01 effective October 1, 2016, beginning with the FY 2017 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 2017 IPPS/LTCH PPS final rule. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), we continued to use the OMB delineations that were adopted beginning with FY 2015 to calculate the area wage indexes, with updates as reflected in OMB Bulletin No. 15–01 specified in the FY 2017 IPPS/LTCH PPS final rule.

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 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. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41362 through 41363), we adopted the updates set forth in OMB Bulletin No. 17–01 effective October 1, 2018, beginning with the FY 2019 wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 17–01, we refer readers to the FY 2019 IPPS/LTCH PPS final rule. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42300 through 42301), we continued 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 and 17–01.

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 material modifications that have a number of downstream effects, such as reclassification changes (as discussed later in this preamble). CMS was unable to complete an extensive review and verification of the changes made by these bulletins until after the development of the FY 2020 IPPS/LTCH PPS proposed rule. 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 OMB Bulletin No. 18–04 may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf*. According to OMB, ''[t]his bulletin 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 (75 FR 37246), and Census Bureau data.'' (We note, 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*), and as discussed in this section of the rule was not issued in time for development of this proposed rule.)

As noted previously, while OMB Bulletin No. 18–04 is not based on new census data, it includes some material changes to the OMB statistical area delineations. Specifically, under the revised OMB delineations, there would be some new CBSAs, urban counties that would become rural, rural counties that would become urban, and some existing CBSAs would be split apart. In addition, the revised OMB delineations would affect various hospital reclassifications, the out-migration adjustment (established by section 505 of Pub. L. 108–173), and treatment of hospitals located in certain rural counties (that is, ''Lugar'' hospitals) under section 1886(d)(8)(B) of the Act. We discuss the revised OMB delineations and the effects of these revisions in this section of this rule. As previously noted, the March 6, 2020 OMB Bulletin 20–01 was not issued in time for development of this proposed rule. While we do not believe that the updates included in OMB Bulletin 20–01 would impact our proposed changes discussed in this section of this rule, if appropriate, we would propose any updates from this bulletin in the FY 2022 IPPS/LTCH PPS proposed rule.

b. Proposed Implementation of Revised Labor Market Area Delineations

We believe that using the revised delineations based on OMB Bulletin No. 18–04 will increase the integrity of the IPPS wage index system by creating a more accurate representation of geographic variations in wage levels. Therefore, we are proposing to implement the revised OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, effective October 1, 2020 beginning with the FY 2021 IPPS wage index. We are proposing to use these revised delineations to calculate area wage indexes in a manner that is generally consistent with the CBSA-based methodologies. Because of the previously described material changes, we also are proposing a wage index transition applicable to hospitals that experience a significant decrease in their FY 2021 wage index compared to their final FY 2020 wage index. This transition is discussed in more detail in this section of this rule.

i. Micropolitan Statistical Areas

As discussed in the FY 2005 IPPS final rule (69 FR 49029 through 49032), 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 areas as Micropolitan Areas. Since FY 2005, we have treated Micropolitian Areas as rural and include hospitals located in Micropolitan Areas in each State's rural wage index. We refer the reader to the FY 2005 IPPS final rule (69 FR 49029 through 19032) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 49952) for a complete discussion regarding this policy and our rationale for treating Micropolitan Areas as rural. For the reasons discussed in the FY 2005 IPPS final rule and in the FY 2015 IPPS final rule, we believe that the best course of action would be to continue this policy and include hospitals located in Micropolitan Areas in each State's rural wage index. Therefore, in conjunction with our proposal to implement the new OMB statistical area delineations beginning in FY 2021, we are proposing to continue to treat Micropolitan Areas as ''rural'' and to include Micropolitan Areas in the calculation of each state's rural wage index.

ii. Urban Counties That Would Become Rural Under the Revised OMB Delineations

As previously discussed, we are proposing to implement the revised OMB statistical area delineations (based upon OMB Bulletin No. 18–04) beginning in FY 2021. Our analysis shows that a total of 34 counties (and county equivalents) and 10 hospitals that were once considered part of an urban CBSA would be considered to be located in a rural area, beginning in FY 2021, under these revised OMB delineations. The following chart lists the 34 urban counties that would be rural if we finalize our proposal to implement the revised OMB delineations.

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FIPS County Code	County/County Equivalent	State	Current CBSA Code	Current CBSA Name
01127	WALKER	AL	13820	Birmingham-Hoover, AL
12045	GULF	FL	37460	Panama City, FL
13007	BAKER	GA	10500	Albany, GA
13235	PULASKI	GA	47580	Warner Robins, GA
15005	KALAWAO	HI	27980	Kahului-Wailuku-Lahaina, HI
17039	DE WITT	IL	14010	Bloomington, IL
17053	FORD	IL	16580	Champaign-Urbana, IL
18143	SCOTT	IN	31140	Louisville/Jefferson County, KY-IN
18179	WELLS	IN	23060	Fort Wayne, IN
19149	PLYMOUTH	IA	43580	Sioux City, IA-NE-SD
20095	KINGMAN	KS	48620	Wichita, KS
21223	TRIMBLE	KY	31140	Louisville/Jefferson County, KY-IN
22119	WEBSTER	LA	43340	Shreveport-Bossier City, LA
26015	BARRY	MI	24340	Grand Rapids-Wyoming, MI
26159	VAN BUREN	MI	28020	Kalamazoo-Portage, MI
27143	SIBLEY	MN	33460	Minneapolis-St. Paul-Bloomington, MN-WI
28009	BENTON	MS	32820	Memphis, TN-MS-AR
29119	MC DONALD	MO	22220	Fayetteville-Springdale-Rogers, AR-MO
30037	GOLDEN VALLEY	MT	13740	Billings, MT
31081	HAMILTON	NE	24260	Grand Island, NE
38085	SIOUX	ND	13900	Bismarck, ND
40079	LE FLORE	OK	22900	Fort Smith, AR-OK
45087	UNION	SC	43900	Spartanburg, SC
46033	CUSTER	SD	39660	Rapid City, SD
47081	HICKMAN	TN	34980	Nashville-Davidson--Murfreesboro--Franklin, TN
48007	ARANSAS	TX	18580	Corpus Christi, TX
48221	HOOD	TX	23104	Fort Worth-Arlington, TX
48351	NEWTON	TX	13140	Beaumont-Port Arthur, TX

FIPS County Code	County/County Equivalent	State	Current CBSA Code	Current CBSA Name
48425	SOMERVELL	TX	23104	Fort Worth-Arlington, TX
51029	BUCKINGHAM	VA	16820	Charlottesville, VA
51033	CAROLINE	VA	40060	Richmond, VA
51063	FLOYD	VA	13980	Blacksburg-Christiansburg-Radford, VA
53013	COLUMBIA	WA	47460	Walla Walla, WA
53051	PEND OREILLE	WA	44060	Spokane-Spokane Valley, WA

We are proposing that the wage data for all hospitals located in the counties, as previously listed, would now be considered rural when calculating their respective State's rural wage index. We recognize that rural areas typically have lower area wage index values than urban areas, and hospitals located in these counties may experience a negative impact in their IPPS payment due to the proposed adoption of the revised OMB delineations. We refer readers to section III.A.2.c. of the preamble of this proposed rule for a discussion of our proposed wage index transition policy to apply a 5 percent cap in FY 2021 for hospitals that may experience any decrease in their final wage index from the prior fiscal year. We are also proposing revisions to the list of counties deemed urban under Section 1886(d)(8)(B) of the Act that will affect the hospitals located in these proposed rural counties. We refer readers to section III.I.3.b for further discussion.

In addition, we note the provisions of § 412.102 of the regulations would continue to apply with respect to determining DSH payments. Specifically, in the first year after a hospital loses urban status, the hospital will receive an adjustment to its DSH payment that equals two-thirds of the difference between the urban DSH payments applicable to the hospital before its redesignation from urban to rural and the rural DSH payments applicable to the hospital subsequent to its redesignation from urban to rural. In the second year after a hospital loses urban status, the hospital will receive an adjustment to its DSH payment that equals one third of the difference between the urban DSH payments applicable to the hospital before its redesignation from urban to rural and the rural DSH payments applicable to the hospital subsequent to its redesignation from urban to rural

iii. Rural Counties That Would Become Urban Under the Revised OMB Delineations

As previously discussed, we are proposing to implement the revised OMB statistical area delineations (based upon OMB Bulletin No. 18–04) beginning in FY 2021. Analysis of these OMB statistical area delineations shows that a total of 47 counties (and county equivalents) and 17 hospitals that were located in rural areas would be located in urban areas under the revised OMB delineations. The following chart lists the 47 rural counties that would be urban if we finalize our proposal to implement the revised OMB delineations.

COUNTIES THAT WOULD GAIN URBAN STATUS

FIPS County Code	County/County Equivalent	State	Proposed CBSA Code	Proposed CBSA Name
01063	GREENE	AL	46220	Tuscaloosa, AL
01129	WASHINGTON	AL	33660	Mobile, AL
05047	FRANKLIN	AR	22900	Fort Smith, AR-OK
12075	LEVY	FL	23540	Gainesville, FL
13259	STEWART	GA	17980	Columbus, GA-AL
13263	TALBOT	GA	17980	Columbus, GA-AL
16077	POWER	ID	38540	Pocatello, ID
17057	FULTON	IL	37900	Peoria, IL
17087	JOHNSON	IL	16060	Carbondale-Marion, IL
18047	FRANKLIN	IN	17140	Cincinnati, OH-KY-IN
18121	PARKE	IN	45460	Terre Haute, IN
18171	WARREN	IN	29200	Lafayette-West Lafayette, IN
19015	BOONE	IA	11180	Ames, IA
19099	JASPER	IA	19780	Des Moines-West Des Moines, IA
20061	GEARY	KS	31740	Manhattan, KS
21043	CARTER	KY	26580	Huntington-Ashland, WV-KY-OH
22007	ASSUMPTION	LA	12940	Baton Rouge, LA

FIPS County Code	County/County Equivalent	State	Proposed CBSA Code	Proposed CBSA Name
22067	MOREHOUSE	LA	33740	Monroe, LA
25011	FRANKLIN	MA	44140	Springfield, MA
26067	IONIA	MI	24340	Grand Rapids-Kentwood, MI
26155	SHIAWASSEE	MI	29620	Lansing-East Lansing, MI
27075	LAKE	MN	20260	Duluth, MN-WI
28031	COVINGTON	MS	25620	Hattiesburg, MS
28051	HOLMES	MS	27140	Jackson, MS
28131	STONE	MS	25060	Gulfport-Biloxi, MS
29053	COOPER	MO	17860	Columbia, MO
29089	HOWARD	MO	17860	Columbia, MO
30095	STILLWATER	MT	13740	Billings, MT
37007	ANSON	NC	16740	Charlotte-Concord-Gastonia, NC-SC
37029	CAMDEN	NC	47260	Virginia Beach-Norfolk-Newport News, VA-NC
37077	GRANVILLE	NC	20500	Durham-Chapel Hill, NC
37085	HARNETT	NC	22180	Fayetteville, NC
39123	OTTAWA	OH	45780	Toledo, OH
45027	CLARENDON	SC	44940	Sumter, SC
47053	GIBSON	TN	27180	Jackson, TN
47161	STEWART	TN	17300	Clarksville, TN-KY
48203	HARRISON	TX	30980	Longview, TX
48431	STERLING	TX	41660	San Angelo, TX
51097	KING AND QUEEN	VA	40060	Richmond, VA
51113	MADISON	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV
51175	SOUTHAMPTON	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC
51620	FRANKLIN CITY	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC
54035	JACKSON	WV	16620	Charleston, WV
54065	MORGAN	WV	25180	Hagerstown-Martinsburg, MD-WV
55069	LINCOLN	WI	48140	Wausau-Weston, WI
72001	ADJUNTAS	PR	38660	Ponce, PR
72083	LAS MARIAS	PR	32420	Mayagüez, PR

We are proposing that when calculating the area wage index, the wage data for hospitals located in these counties would be included in their new respective urban CBSAs. Typically, hospitals located in an urban area would receive a wage index value higher than or equal to hospitals located in their State's rural area. We refer readers to section III.A.2.c. of the preamble of this proposed rule for a discussion of our proposed wage index transition policy to apply a 5 percent cap in FY 2021 for hospitals that may experience any decrease in their final wage index from the prior fiscal year.

We also note that due to the proposed adoption of the revised OMB delineations, some CAHs that were previously located in rural areas may be located in urban areas. The regulations at §§ 412.103(a)(6) and 485.610(b)(5) provide affected CAHs with a two-year transition period that begins from the

date the redesignation becomes effective. The affected CAHs must reclassify as rural during this transition period in order to retain their CAH status after the two-year transition period ends. We refer readers to the FY 2015 IPPS/LTCH final rule (79 FR 50162 and 50163) for further discussion of the two-year transition period for CAHs.

iv. Urban Counties That Would Move to a Different Urban CBSA Under the Revised OMB Delineations

In addition to rural counties becoming urban and urban counties becoming rural, some urban counties would shift from one urban CBSA to another urban CBSA under our proposal to adopt the new OMB delineations. In other cases, adopting the revised OMB delineations would involve a change only in CBSA name and/or number, while the CBSA continues to encompass the same constituent counties. For example, CBSA 19380 (Dayton, OH) would experience both a change to its number and its name, and become CBSA 19430 (Dayton-Kettering, OH), while all of its three constituent counties would remain the same. In other cases, only the name of the CBSA would be modified, and none of the currently assigned counties would be reassigned to a different urban CBSA. The following is a list of such CBSAs where we are proposing to change the name and/or CBSA number only.

URBAN AREAS WITH CBSA NAME AND/OR NUMBER CHANGE

Current CBSA Code	Current CBSA Name	Proposed CBSA Code	Proposed CBSA Name
10540	Albany, OR	10540	Albany-Lebanon, OR
11500	Anniston-Oxford-Jacksonville, AL	11500	Anniston-Oxford, AL
12060	Atlanta-Sandy Springs-Roswell, GA	12060	Atlanta-Sandy Springs-Alpharetta, GA
12420	Austin-Round Rock, TX	12420	Austin-Round Rock-Georgetown, TX
13460	Bend-Redmond, OR	13460	Bend, OR
13980	Blacksburg-Christiansburg-Radford, VA	13980	Blacksburg-Christiansburg, VA
14740	Bremerton-Silverdale, WA	14740	Bremerton-Silverdale-Port Orchard, WA
15380	Buffalo-Cheektowaga-Niagara Falls, NY	15380	Buffalo-Cheektowaga, NY
19380	Dayton, OH	19430	Dayton-Kettering, OH
24340	Grand Rapids-Wyoming, MI	24340	Grand Rapids-Kentwood, MI
24860	Greenville-Anderson-Mauldin, SC	24860	Greenville-Anderson, SC
25060	Gulfport-Biloxi-Pascagoula, MS	25060	Gulfport-Biloxi, MS
25540	Hartford-West Hartford-East Hartford, CT	25540	Hartford-East Hartford-Middletown, CT
25940	Hilton Head Island-Bluffton-Beaufort, SC	25940	Hilton Head Island-Bluffton, SC
28700	Kingsport-Bristol-Bristol, TN-VA	28700	Kingsport-Bristol, TN-VA
31860	Mankato-North Mankato, MN	31860	Mankato, MN
33340	Milwaukee-Waukesha-West Allis, WI	33340	Milwaukee-Waukesha, WI
34940	Naples-Immokalee-Marco Island, FL	34940	Naples-Marco Island, FL

Current CBSA Code	Current CBSA Name	Proposed CBSA Code	Proposed CBSA Name
35660	Niles-Benton Harbor, MI	35660	Niles, MI
36084	Oakland-Hayward-Berkeley, CA	36084	Oakland-Berkeley-Livermore, CA
36500	Olympia-Tumwater, WA	36500	Olympia-Lacey-Tumwater, WA
38060	Phoenix-Mesa-Scottsdale, AZ	38060	Phoenix-Mesa-Chandler, AZ
39140	Prescott, AZ	39150	Prescott Valley-Prescott, AZ
43524	Silver Spring-Frederick-Rockville, MD	23224	Frederick-Gaithersburg-Rockville, MD
44420	Staunton-Waynesboro, VA	44420	Staunton, VA
44700	Stockton-Lodi, CA	44700	Stockton, CA
45940	Trenton, NJ	45940	Trenton-Princeton, NJ
46700	Vallejo-Fairfield, CA	46700	Vallejo, CA
47300	Visalia-Porterville, CA	47300	Visalia, CA
48140	Wausau, WI	48140	Wausau-Weston, WI
48424	West Palm Beach-Boca Raton-Delray Beach, FL	48424	West Palm Beach-Boca Raton-Boynton Beach, FL

We are not discussing further in this section these proposed changes because they are inconsequential changes with respect to the IPPS wage index. However, in other cases, if we adopt the revised OMB delineations, counties would shift between existing and new CBSAs, changing the constituent makeup of the CBSAs. For example, Kendall County, IL would be moved from the current CBSA 16974 (Chicago-Naperville-Arlington Height, IL) into proposed CBSA 20994 (Elgin, IL). The remaining counties in the current CBSA 16974 would be assigned to the proposed CBSA 16984 (Chicago-Naperville-Evanston, IL). The constituent counties of CBSA 16974 would therefore be split into two different urban CBSAs. There would also be a significant rearrangement in the constituent counties among the New York City Area Metropolitan Divisions. Most notably, Monmouth, Middlesex, and Ocean Counties in NJ would move from the current CBSA 35614 (New York-Jersey City-White Plains, NY-NJ) to the proposed CBSA 35154 (New Brunswick-Lakewood, NJ). Also, Somerset County, NJ would move from current CBSA 35084 (Newark, NJ-PA) to CBSA 35154. The following chart lists the urban counties that would move from one urban CBSA to a newly proposed or modified CBSA if we adopted the revised OMB delineations.

COUNTIES THAT WOULD CHANGE TO ANOTHER CBSA

FIPS County Code	County/County Equivalent	State	Current CBSA Code	Current CBSA Name	Proposed CBSA Code	Proposed CBSA Name
17031	COOK	IL	16974	Chicago-Naperville-Arlington Heights, IL	16984	Chicago-Naperville-Evanston, IL
17043	DU PAGE	IL	16974	Chicago-Naperville-Arlington Heights, IL	16984	Chicago-Naperville-Evanston, IL
17063	GRUNDY	IL	16974	Chicago-Naperville-Arlington Heights, IL	16984	Chicago-Naperville-Evanston, IL
17093	KENDALL	IL	16974	Chicago-Naperville-Arlington Heights, IL	20994	Elgin, IL
17111	MC HENRY	IL	16974	Chicago-Naperville-Arlington Heights, IL	16984	Chicago-Naperville-Evanston, IL
17197	WILL	IL	16974	Chicago-Naperville-Arlington Heights, IL	16984	Chicago-Naperville-Evanston, IL
34023	MIDDLESEX	NJ	35614	New York-Jersey City-White Plains, NY-NJ	35154	New Brunswick-Lakewood, NJ
34025	MONMOUTH	NJ	35614	New York-Jersey City-White Plains, NY-NJ	35154	New Brunswick-Lakewood, NJ
34029	OCEAN	NJ	35614	New York-Jersey City-White Plains, NY-NJ	35154	New Brunswick-Lakewood, NJ
34035	SOMERSET	NJ	35084	Newark, NJ-PA	35154	New Brunswick-Lakewood, NJ
36027	DUTCHESS	NY	20524	Dutchess County-Putnam County, NY	39100	Poughkeepsie-Newburgh-Middletown, NY
36071	ORANGE	NY	35614	New York-Jersey City-White Plains, NY-NJ	39100	Poughkeepsie-Newburgh-Middletown, NY
36079	PUTNAM	NY	20524	Dutchess County-Putnam County, NY	35614	New York-Jersey City-White Plains, NY-NJ
47057	GRAINGER	TN	28940	Knoxville, TN	34100	Morristown, TN
54043	LINCOLN	WV	26580	Huntington-Ashland, WV-KY-OH	16620	Charleston, WV
72055	GUANICA	PR	38660	Ponce, PR	49500	Yauco, PR
72059	GUAYANILLA	PR	38660	Ponce, PR	49500	Yauco, PR
72111	PENUELAS	PR	38660	Ponce, PR	49500	Yauco, PR
72153	YAUCO	PR	38660	Ponce, PR	49500	Yauco, PR

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If hospitals located in these counties move from one CBSA to another under the revised OMB delineations, there may be impacts, both negative and positive, upon their specific wage index values. We refer readers to section III.A.2.c. of the preamble of this proposed rule for a discussion of our proposed wage index transition policy to apply a 5 percent cap in FY 2021 for hospitals that may experience any decrease in their final wage index from the prior fiscal year. We also refer readers to section III.I.2.c. of the preamble of this proposed rule for discussion of our proposals to reassign MGCRB wage index reclassifications for

hospitals currently assigned to these modified CBSAs.

c. Proposed Transition for Hospitals Negatively Impacted

Overall, we believe implementing the revised OMB statistical area delineations would result in wage index values being more representative of the actual costs of labor in a given area. However, we recognize that some hospitals would experience decreases in wage index values as a result of our proposed implementation of the revised labor market area delineations. We also realize that some hospitals would have higher wage index values due to our proposed implementation of the new labor market area delineations.

In the past, we have proposed and finalized budget neutral transition policies to help mitigate negative impacts on hospitals of certain wage index proposals. For example, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49960 through 49963) when we implemented new OMB delineations based on the 2010 decennial census data, we finalized budget neutral transitions for certain situations. Specifically, in the FY 2015 IPPS/LTCH PPS final rule, for a period of 3 fiscal years, we allowed urban hospitals that became rural under the new delineations (and that had no form of wage index reclassification or redesignation) to maintain the wage index value of the CBSA in which they were physically located for FY 2014; and for hospitals that experienced a decrease in wage index values due to the change in labor market area definitions, we implemented a 1-year blended wage index where hospitals received 50 percent of their wage index based on the new OMB delineations that went into effect in FY 2015, and 50 percent of their wage index based on their FY 2014 labor market area. This blended wage index required us to calculate wage indexes for all hospitals using both old and new labor market definitions even though it only applied to hospitals that experienced a decrease in wage index values due to a change in labor market area definitions. More recently, in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42336 through 42338), we finalized a wage index transition to help mitigate any significant decreases in the wage index values of hospitals compared to their final wage index value from the prior fiscal year due to the combined effect of the proposed changes to the FY 2020 wage index. Specifically, for FY 2020, we implemented a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in FY 2019.

As previously mentioned, while the revised OMB delineations in this latest OMB bulletin (OMB Bulletin 18–04) are not based on new census data, there were some material changes in the OMB delineations. Also, as previously mentioned, the revisions in the latest OMB bulletin are updates to the CBSA delineations already adopted in FY 2015 based on the 2010 census data. For these reasons, for FY 2021 we do not believe it is necessary to implement the multifaceted transitions we established in FY 2015 for the adoption of the new OMB delineations based on the new decennial census data. However, in accordance with our past practice of implementing transition policies to help mitigate negative impacts on hospitals of certain wage index proposals, we do believe that if we adopt the proposed revised OMB delineations, it would be appropriate to implement a transition policy since, as previously mentioned, some of these revisions are material, and may negatively impact payments to hospitals. For example, changes in the county makeup of a CBSA, by adding or removing a constituent county, may change the pool of hospitals contributing average hourly wage data, potentially resulting in lower wage index values for certain areas. When CMS implemented various changes to the hospital wage index in prior rulemaking, commenters frequently supported transition policies that ensured wage index values maintain a degree of year-to-year consistency (see comments to our FY 2015 IPPS/LTCH PPS final rule transition policies at 79 FR 49959 through 49961). Thus, we believe applying a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index from the prior fiscal year, as we did for FY 2020, would be an appropriate transition for FY 2021 for the revised OMB delineations as it provides predictability in payment levels from FY 2020 to the upcoming FY 2021. The proposed FY 2021 5-percent cap on wage index decreases would be applied to all hospitals that have any decrease in their wage indexes, mitigating significant negative decrease in wage index values. Given the significant portion of Medicare IPPS payments that are adjusted by the wage index and how relatively few hospitals generally see wage index declines in excess of 5 percent, hospitals may have difficulty adapting to changes in the wage index of this magnitude all at once. For these reasons, for FY 2021, we would place a 5 percent cap on any decrease in a hospital's wage index from the hospital's final wage index for FY 2020, such 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. This transition would allow the effects of our proposed adoption of the revised CBSA delineations to be phased in over 2 years with no estimated reduction in the wage index of more than 5 percent in FY 2021 (that is, no cap would be applied the second year). We continue to believe 5 percent is a reasonable level for the cap because it would effectively mitigate any significant decreases in the wage index for FY 2021. We also believe this transition would afford hospitals adequate time to fully assess any additional reclassification options available to them (we refer the reader to section III.I.2.c. of the preamble of this proposed rule for a complete discussion regarding the revised OMB delineations and their effects regarding hospital reclassification). Therefore, for FY 2021, we are proposing to again provide for a transition of a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index from the prior fiscal year (FY 2020). Consistent with the application of the 5 percent cap in FY 2020, the proposed FY 2021 5-percent cap on wage index decreases would be applied to all hospitals that have any decrease in their wage indexes, regardless of the circumstance causing the decline, so that a hospital's final wage index for FY 2021 will not be less than 95 percent of its final wage index for FY 2020. We believe applying the cap on wage index decreases for all hospitals, regardless of the circumstance causing the decrease, allows CMS to mitigate any significant negative impacts of adopting the new OMB delineations in a manner that is readily identifiable in the wage index tables and promotes greater wage index predictability.

d. Proposed Transition Budget Neutrality

For FY 2021 we are proposing to apply a budget neutrality adjustment to the standardized amount so that our proposed transition described in section III.A.2.c. is implemented in a budget neutral manner under our authority in section 1886(d)(5)(I) of the Act. We note that implementing the proposed transition wage index in a budget neutral manner is consistent with past practice (for example, 79 FR 50372 and 84 FR 42338) where CMS has used its exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to budget neutralize transition wage index policies when such policies allow

for the application of a transitional wage index only when it benefits the hospital. We stated that we believed, and continue to believe, that it would be appropriate to ensure that such policies do not increase estimated aggregate Medicare payments beyond the payments that would be made had we never proposed these transition policies (79 FR 50372 and 84 FR 42337 through 42338). Therefore, for FY 2021, we are proposing to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to apply a budget neutrality adjustment to the standardized amount so that our proposed transition (described in section III.A.2.c.) is implemented in a budget neutral manner.

Specifically, we are proposing to apply a budget neutrality adjustment to ensure that estimated aggregate payments under our proposed transition (described in section III.A.2.c. of the preamble of this proposed rule) for hospitals that have any decrease in their wage indexes for FY 2021 would equal what estimated aggregate payments would have been without the proposed transition. To determine the associated budget neutrality factor, we compared estimated aggregate IPPS payments with and without the proposed transition.

Based on this proposed rule data, the budget neutrality adjustment factor to achieve budget neutrality for the proposed transition would be 0.998580, which would be applied to the FY 2021 standardized amount. We note that this number would be updated, as appropriate, based on the final rule data. We refer readers to the Addendum of this final rule for further information regarding the budget neutrality calculations.

We note that, consistent with past practice (69 FR 49034 and 79 FR 49963), we are not adopting the revised OMB delineations themselves in a budget neutral manner. We do not believe that the revision to the labor market areas in and of itself constitutes an ''adjustment or update'' to the adjustment for area wage differences, as provided under section 1886(d)(3)(E) of the Act.

3. Codes for Constituent Counties in CBSAs

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. There are two different lists of codes associated with counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS has listed and used SSA and FIPS county codes to identify and crosswalk counties to CBSA codes for purposes of the hospital wage index. As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130), we have learned that SSA county codes are no longer being maintained and updated. However, the FIPS codes continue to be maintained by the U.S. Census Bureau. We believe that using the latest FIPS codes will allow us to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions.

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*. We believe that it is important to use the latest counties or county equivalent entities in order to properly crosswalk hospitals from a county to a CBSA for purposes of the hospital wage index used under the IPPS.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130), we adopted a policy to discontinue the use of the SSA county codes and began using only the FIPS county codes for purposes of crosswalking counties to CBSAs. In addition, in the same rule, we implemented the latest FIPS code updates which were effective October 1, 2017, beginning with the FY 2018 wage indexes. These updates have been used to calculate the wage indexes in a manner generally consistent with the CBSA-based methodologies finalized in the FY 2005 IPPS final rule and the FY 2015 IPPS/LTCH PPS final rule.

For FY 2021, we are continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs. For FY 2021, Tables 2 and 3 associated with this proposed rule and the County to CBSA Crosswalk File and Urban CBSAs and Constituent Counties for Acute Care Hospitals File posted on the CMS website reflect these county changes.

B. Worksheet S–3 Wage Data for the Proposed FY 2021 Wage Index

The proposed FY 2021 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2017 (the FY 2020 wage indexes were based on data from cost reporting periods beginning during FY 2016).

1. Included Categories of Costs

The proposed FY 2021 wage index includes all of the following categories of data associated with costs paid under the IPPS (as well as outpatient costs):

- Salaries and hours from short-term, acute care hospitals (including paid lunch hours and hours associated with military leave and jury duty);
- Home office costs and hours;
- Certain contract labor costs and hours, which include direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services, and certain contract indirect patient care services (as discussed in the FY 2008 final rule with comment period (72 FR 47315 through 47317)); and
- Wage-related costs, including pension costs (based on policies adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590)) and other deferred compensation costs.

2. Excluded Categories of Costs

Consistent with the wage index methodology for FY 2020, the proposed wage index for FY 2021 also excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as skilled nursing facility (SNF) services, home health services, costs related to GME (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The proposed FY 2021 wage index also excludes the salaries, hours, and wage-related costs of hospital-based rural health clinics (RHCs), and Federally qualified health centers (FQHCs) because Medicare pays for these costs outside of the IPPS (68 FR 45395). In addition, salaries, hours, and wage-related costs of CAHs are excluded from the wage index for the reasons explained in the FY 2004 IPPS final rule (68 FR 45397 through 45398). For FY 2020 and subsequent years, other wage-related costs are also excluded from the calculation of the wage index. As discussed in the FY 2019 IPPS/LTCH final rule (83 FR 41365 through 41369), other wage-related costs reported on Worksheet S–3, Part II, Line 18 and Worksheet S–3, Part IV, Line 25 and subscripts, as well as all other wage-related costs, such as contract labor costs, are excluded from the calculation of the wage index.

3. Use of Wage Index Data by Suppliers and Providers Other Than Acute Care Hospitals Under the IPPS

Data collected for the IPPS wage index also are currently used to calculate wage indexes applicable to suppliers and other providers, such as SNFs, home health agencies (HHAs), ambulatory surgical centers (ASCs), and

hospices. In addition, they are used for prospective payments to IRFs, IPFs, and LTCHs, and for hospital outpatient services. We note that, in the IPPS rules, we do not address comments pertaining to the wage indexes of any supplier or provider except IPPS providers and LTCHs. Such comments should be made in response to separate proposed rules for those suppliers and providers.

4. Proper Documentation of Physician Time Spent in Part A Administrative Versus Part B Billable Activities

In the last few years, we have received wage index data appeals related to MACs' disallowances of wages and hours that hospitals believe are associated with Part A administrative physician time, but the MACs believe are not properly documented as such, or are in fact, associated with Part B billable activities, which are not included in the wage index. For physicians employed by a hospital, their salaries and hours associated with Part A administrative time, which ARE included in the wage index, are reported on CMS–2552–10 Worksheet S–3, Part II, line 4, and the salaries and hours of hospital employed physicians associated with billable Part B patient care activities, which are NOT included in the wage index, are reported on Worksheet S–3, Part II, line 5. Specifically, the instructions for lines 4 and 5 state the following:

- *Line 4*—Enter the physician Part A administrative salaries, (excluding teaching physician salaries), that are included in line 1. Also do not include intern and resident (I & R) salary on this line. Report I & R salary on line 7. Subscript this line and report salaries for Part A teaching physicians on line 4.01.
- *Line 5*—Enter the total physician, physician assistant, nurse practitioner and clinical nurse specialist on-call salaries and salaries billed under Part B that are included in line 1. Under Medicare, these services are related to direct patient care and billed separately under Part B. Also include physician salaries for patient care services reported for rural health clinics (RHC) and FQHCs included on Worksheet A, column 1, lines 88 and/or 89 as applicable. Do not include on this line amounts that are included on lines 9 and 10 for the SNF or excluded area salaries. Refer to CMS Pub. 15–1, sections 2313.2.E. and 2182.3.E., for instructions related to keeping time studies to track time spent in Part A versus Part B activities. However, although section 2313.2.E.2. states that, ''A minimally acceptable time study must encompass at least one full week per month of the cost reporting period,'' the contractor makes the final determination on the adequacy of the records maintained. A 2-week semi-annual (every 6 months) time study can be adequate unless the contractor believes that a significant change in the pattern of physician time is likely to occur from one quarter to the next, in which case, the contractor may require more frequent time studies. Adequate documentation must be maintained to support total hours in a manner that is verifiable, and to serve as a condition of payment under Part A.

In addition, for physicians that are not employed by the hospital but are under contract, the wages and hours associated with contract Physician Part A administrative activities are reported on Worksheet S–3, Part II, line 13. No salaries and hours related to Part B activities are allowed. Line 13 states the following:

Line 13—Enter from your records the amount paid under contract (in accordance with the general instructions for contract labor) for Part A physician services—administrative, excluding teaching physician services. DO NOT include contract I & R services (to be included on line 7). DO NOT include the costs for Part A physician services from the home office allocation and/or from related organizations (to be reported on line 15). Do not include wages or hours associated with Part B services. As stated in the General Instructions for Contract Labor, ''the minimum requirement for supporting documentation is the contract itself. If the wage costs, hours, and non-labor costs are not clearly specified in the contract, other supporting documentation is required, such as a representative sample of invoices that specify the wage costs, hours, and non-labor costs.'' Refer to CMS Pub. 15–1, sections 2313.2E and 2182.3.E, for instructions related to keeping time studies to track time spent in Part A versus Part B activities. Adequate documentation must be maintained to support total hours in a manner that is verifiable.

In order to accurately report the wages and hours associated with Part A and Part B activities on lines 4 and 5 and 13 respectively, the providers are required to maintain records as to the allocation of physicians' time between various services to keep track of the amount of time the physicians spend on Part A versus Part B activities. 42 CFR 415.60(b) and CMS Pub. 15–1, chapter 21, section 2182.3.B. Specifically, 42 CFR 415.60(b) states, except as provided in paragraph (d) of the section, each provider that incurs physician compensation costs must allocate those costs, in proportion to the percentage of total time that is spent in furnishing each category of services, among—

- Physician services to the provider (as described in § 415.55);
- Physician services to patients (as described in § 415.102); and
- Activities of the physician, such as funded research, that are not paid under either Part A or Part B of Medicare.

To facilitate the MAC's review of whether physician wages and hours have been reported correctly, hospitals must submit the physician allocation agreements to the MAC. (See CMS Pub. 15–1, Section 2182.3.E.3. which states that allocation agreements are to be submitted annually as part of the cost report filing process.) In the absence of a written allocation agreement (such as Exhibit 1 in CMS Pub. 15–II, Chapter 40, Section 4004.2 and related instructions for this exhibit on Line 34 of Section 4004.2—that is, instructions for Form CMS–2552–10, Worksheet S–2, Part II, line 34), the MAC assumes that 100 percent of the physician compensation cost is allocated to Part B services (see 42 CFR 415.60(f)(2)). The hospital must maintain the information used to complete the physician allocation agreements as directed in CMS Pub. 15–1 section 2182.3.E. in order to track time spent in Part A versus Part B activities. This section specifies that the hospital may choose to employ the methodology described in subsection 2313.2.E for a time study but may not be required by the MAC to utilize that specific methodology. Therefore, although section 2313.2.E. states that ''a minimally acceptable time study must encompass at least one full week per month of the cost reporting period,'' the MAC makes the final determination on the adequacy of the records maintained for the allocation of physicians' compensation. A 2-week semi-annual (every 6 months) time study can be adequate unless the MAC believes that a significant change in the pattern of physician time is likely to occur from one quarter to the next, in which case, the MAC may require more frequent time studies (see CMS–2552–10, Worksheet S–3, Part II line 5 instructions). Adequate documentation must be maintained to support total hours in a manner that is verifiable, and to serve as a condition of payment under Part A, that is, total hours worked by the physicians must be based on actual data accumulated during the cost reporting period and may not be imputed (consistent with 42 CFR 413.24 and 415.60(f)(1) and (g)). Non-allowable services that are neither Part A nor Part B services (for example, research,

teaching of residents in non-approved programs, teaching and supervision of medical students, writing for medical journals, reasonable availability services in departments/cost centers other than Emergency Room, etc.) are reported as non-reimbursable activities in the designated non-reimbursable cost centers of the Medicare cost report, CMS–2552–10 (for example, Worksheet A, lines 190–194, see 42 CFR 415.60(b)(3)). Reasonable availability services for emergency rooms can be considered Part A in certain circumstances (see PRM–I, section 2109.3.A. through C. for instances when emergency department physician availability services costs are allowable, and for the associated required documentation).

C. Verification of Worksheet S–3 Wage Data

The wage data for the FY 2021 wage index were obtained from Worksheet S–3, Parts II and III of the Medicare cost report (Form CMS–2552–10, OMB Control Number 0938–0050 with expiration date March 31, 2022) for cost reporting periods beginning on or after October 1, 2016, and before October 1, 2017. For wage index purposes, we refer to cost reports during this period as the ''FY 2017 cost report,'' the ''FY 2017 wage data,'' or the ''FY 2017 data.'' Instructions for completing the wage index sections of Worksheet S–3 are included in the Provider Reimbursement Manual (PRM), Part 2 (Pub. 15–2), Chapter 40, Sections 4005.2 through 4005.4. The data file used to construct the FY 2021 wage index includes FY 2017 data submitted to us as of February 7, 2019. As in past years, we performed an extensive review of the wage data, mostly through the use of edits designed to identify aberrant data.

We asked our MACs to revise or verify data elements that result in specific edit failures. For the proposed FY 2021 wage index, we identified and excluded 84 providers with aberrant data that should not be included in the wage index. However, if data elements for some of these providers are corrected, we intend to include data from those providers in the final FY 2021 wage index. We also adjusted certain aberrant data and included these data in the proposed wage index. For example, in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). We instructed MACs to complete their data verification of questionable data elements and to transmit any changes to the wage data no later than March 19, 2020.

In constructing the proposed FY 2021 wage index, we included the wage data for facilities that were IPPS hospitals in FY 2017, inclusive of those facilities that have since terminated their participation in the program as hospitals, as long as those data did not fail any of our edits for reasonableness. We believe including the wage data for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period and to ensure that the current wage index represents the labor market area's current wages as compared to the national average of wages. However, we excluded the wage data for CAHs as discussed in the FY 2004 IPPS final rule (68 FR 45397 through 45398); that is, any hospital that is designated as a CAH by 7 days prior to the publication of the preliminary wage index public use file (PUF) is excluded from the calculation of the wage index. For the proposed rule, we removed 8 hospitals that converted to CAH status on or after January 24, 2019, the cut-off date for CAH exclusion from the FY 2020 wage index, and through and including January 24, 2020, the cut-off date for CAH exclusion from the FY 2021 wage index. In summary, we calculated the proposed wage index using the Worksheet S–3, Parts II and III wage data of 3,196 hospitals.

For the proposed FY 2021 wage index, we allotted the wages and hours data for a multicampus hospital among the different labor market areas where its campuses are located using campus full-time equivalent (FTE) percentages as originally finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51591). Table 2, which contains the proposed FY 2021 wage index associated with this proposed rule (available via the internet on the CMS website), includes separate wage data for the campuses of 16 multicampus hospitals. The following chart lists the multicampus hospitals by CSA certification number (CCN) and the FTE percentages on which the wages and hours of each campus were allotted to their respective labor market areas:

CCN of Multicampus Hospital	Full-Time Equivalent (FTE) Percentages
050121	0.82
05B121	0.18
070033	0.93
07B033	0.07
100029	0.54
10B029	0.46
100167	0.38
10B167	0.62
140010	0.82
14B010	0.18
220074	0.89
22B074	0.11
330195	0.89
33B195	0.11
330234	0.74
33B234	0.26
340115	0.95
34B115	0.05
360020	0.97
36B020	0.03
390006	0.94
39B006	0.06
390115	0.85
39B115	0.15
390142	0.83
39B142	0.17
460051	0.82
46B051	0.18
510022	0.95
51B022	0.05
670062	0.59
67B062	0.41

We note that, in past years, in Table 2, we have placed a ''B'' to designate the subordinate campus in the fourth position of the hospital CCN. However, for the FY 2019 IPPS/LTCH PPS proposed and final rules and subsequent rules, we have moved the ''B'' to the third position of the CCN. Because all IPPS hospitals have a ''0'' in the third position of the CCN, we believe that placement of the ''B'' in this third position, instead of the ''0'' for the subordinate campus, is the most efficient method of identification and interferes the least with the other, variable, digits in the CCN.

D. Method for Computing the Proposed FY 2021 Unadjusted Wage Index

The method used to compute the proposed FY 2021 wage index without an occupational mix adjustment follows the same methodology that we used to compute the wage indexes without an occupational mix adjustment in the FY 2020 IPPS/LTCH PPS final rule (see 84 FR 42304 through 42307, August 16, 2019), and we are not proposing any changes to this methodology. We have restated our methodology in this section of this rule.

Step 1.—We gathered data from each of the non-Federal, short-term, acute care hospitals for which data were reported on the Worksheet S–3, Parts II and III of the Medicare cost report for the hospital's cost reporting period relevant to the proposed wage index (in this case, for FY 2021, these were data from cost reports for cost reporting periods beginning on or after October 1, 2016, and before October 1, 2017). In addition, we included data from some hospitals that had cost reporting periods beginning before October 2016 and reported a cost reporting period covering all of FY 2017. These data were included because no other data from these hospitals would be available for the cost reporting period as previously described, and because particular labor market areas might be affected due to the omission of these hospitals. However, we generally describe these wage data as FY 2017 data. We note that, if a hospital had more than one cost reporting period beginning during FY 2017 (for example, a hospital had two short cost reporting periods beginning on or after October 1, 2016, and before October 1, 2017), we include wage data from only one of the cost reporting periods, the longer, in the wage index calculation. If there was more than one cost reporting period and the periods were equal in length, we included the wage data from the later period in the wage index calculation.

Step 2.—Salaries.—The method used to compute a hospital's average hourly wage excludes certain costs that are not paid under the IPPS. (We note that, beginning with FY 2008 (72 FR 47315), we included what were then Lines 22.01, 26.01, and 27.01 of Worksheet S–3, Part II of CMS Form 2552–96 for overhead services in the wage index. Currently, these lines are lines 28, 33, and 35 on CMS Form 2552–10. However, we note that the wages and hours on these lines are not incorporated into Line 101, Column 1 of Worksheet A, which, through the electronic cost reporting software, flows directly to Line 1 of Worksheet S–3, Part II. Therefore, the first step in the wage index calculation is to compute a ''revised'' Line 1, by adding to the Line 1 on Worksheet S–3, Part II (for wages and hours respectively) the amounts on Lines 28, 33, and 35.) In calculating a hospital's Net Salaries (we note that we previously used the term ''average'' salaries in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51592), but we now use the term ''net'' salaries) plus wage-related costs, we first compute the following: Subtract from Line 1 (total salaries) the GME and CRNA costs reported on CMS Form 2552–10, Lines 2, 4.01, 7, and 7.01, the Part B salaries reported on Lines 3, 5 and 6, home office salaries reported on Line 8, and exclude salaries reported on Lines 9 and 10 (that is, direct salaries attributable to SNF services, home health services, and other subprovider components not subject to the IPPS). We also subtract from Line 1 the salaries for which no hours were reported. Therefore, the formula for Net Salaries (from Worksheet S–3, Part II) is the following: ((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)).

To determine Total Salaries plus Wage-Related Costs, we add to the Net Salaries the costs of contract labor for direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services (Lines 11, 12 and 13), home office salaries and wage-related costs reported by the hospital on Lines 14.01, 14.02, and 15, and nonexcluded area wage-related costs (Lines 17, 22, 25.50, 25.51, and 25.52). We note that contract labor and home office salaries for which no corresponding hours are reported are not included. In addition, wage-related costs for nonteaching physician Part A employees (Line 22) are excluded if no corresponding salaries are reported for those employees on Line 4. The formula for Total Salaries plus Wage-Related Costs (from Worksheet S–3, Part II) is the following: ((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)) + (Line 11 + Line 12 + Line 13 + Line 14.01 + 14.02 + Line 15) + (Line 17 + Line 22 + 25.50 + 25.51 + 25.52).

Step 3.—Hours.—With the exception of wage-related costs, for which there are no associated hours, we compute total hours using the same methods as described for salaries in Step 2. The formula for Total Hours (from Worksheet S–3, Part II) is the following: ((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)) + (Line 11 + Line 12 + Line 13 + Line 14.01 + 14.02 + Line 15).

Step 4.—For each hospital reporting both total overhead salaries and total overhead hours greater than zero, we then allocate overhead costs to areas of the hospital excluded from the wage index calculation. First, we determine the ''excluded rate'', which is the ratio of excluded area hours to Revised Total Hours (from Worksheet S–3, Part II) with the following formula: (Line 9 + Line 10)/(Line 1 + Line 28 + Line 33 + Line 35) − (Lines 2, 3, 4.01, 5, 6, 7, 7.01, and 8 and Lines 26 through 43). We then compute the amounts of overhead salaries and hours to be allocated to excluded areas by multiplying the above ratio by the total overhead salaries and hours reported on Lines 26 through 43 of Worksheet S–3, Part II. Next, we compute the amounts of overhead wage-related costs to be allocated to excluded areas using three steps:

- We determine the ''overhead rate'' (from Worksheet S–3, Part II), which is the ratio of overhead hours (Lines 26 through 43 minus the sum of Lines 28, 33, and 35) to revised hours excluding the sum of lines 28, 33, and 35 (Line 1 minus the sum of Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, 9, 10, 28, 33, and 35). We note that, for the FY 2008 and subsequent wage index calculations, we have been excluding the overhead contract labor (Lines 28, 33, and 35) from the determination of the ratio of overhead hours to revised hours because hospitals typically do not provide fringe benefits (wage-related costs) to contract personnel. Therefore, it is not necessary for the wage index calculation to exclude overhead wage-related costs for contract personnel. Further, if a hospital does contribute to wage-related costs for contracted personnel, the instructions for Lines 28, 33, and 35 require that associated wage-related costs be combined with wages on the respective contract labor lines. The formula for the Overhead Rate (from Worksheet S–3, Part II) is the following: (Lines 26 through 43 − Lines 28, 33 and 35)/((((Line 1 + Lines 28, 33, 35) − (Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, and 26 through 43)) − (Lines 9 and 10)) + (Lines 26 through 43 − Lines 28, 33, and 35)).
- We compute overhead wage-related costs by multiplying the overhead hours ratio by wage-related costs reported on Part II, Lines 17, 22, 25.50, 25.51, and 25.52.
- We multiply the computed overhead wage-related costs by the previously described excluded area hours ratio.

Finally, we subtract the computed overhead salaries, wage-related costs, and hours associated with excluded areas from the total salaries (plus wage-related costs) and hours derived in Steps 2 and 3.

Step 5.—For each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2016 through April 15, 2018, for private industry hospital workers from the BLS' Compensation and Working Conditions. We use the ECI because it reflects the price increase associated with total compensation (salaries plus fringes) rather than just the increase in salaries. In addition, the ECI includes managers as well as other hospital workers. This methodology to compute the monthly update factors uses actual quarterly ECI data and assures that the update factors match the actual quarterly and annual percent changes. We also note that, since April 2006 with the publication of March 2006 data, the BLS' ECI uses a different classification system, the North American Industrial Classification System (NAICS), instead of the Standard Industrial Codes (SICs), which no longer exist. We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we are not proposing to make any changes to the usage of the ECI for FY 2021. The factors used to adjust the hospital's data are based on the midpoint of the cost reporting period, as indicated in this rule.

Step 6.—Each hospital is assigned to its appropriate urban or rural labor market area before any reclassifications under section 1886(d)(8)(B), 1886(d)(8)(E), or 1886(d)(10) of the Act. Within each urban or rural labor market area, we add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in that area to determine the total adjusted salaries plus wage-related costs for the labor market area.

Step 7.—We divide the total adjusted salaries plus wage-related costs obtained under Step 6 by the sum of the corresponding total hours (from Step 4) for all hospitals in each labor market area to determine an average hourly wage for the area.

Step 8.—We add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in the Nation and then divide the sum by the national sum of total hours from Step 4 to arrive at a national average hourly wage.

Step 9.—For each urban or rural labor market area, we calculate the hospital wage index value, unadjusted for occupational mix, by dividing the area average hourly wage obtained in Step 7 by the national average hourly wage computed in Step 8.

Step 10.—For each urban labor market area for which we do not have any hospital wage data (either because there are no IPPS hospitals in that labor market area, or there are IPPS hospitals in that area but their data are either too new to be reflected in the current year's wage index calculation, or their data are aberrant and are deleted from the wage index), we finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42305) that, for FY 2020 and subsequent years' wage index calculations, such CBSA's wage index would be equal to total urban salaries plus wage-related costs (from Step 5) in the State, divided by the total urban hours (from Step 4) in the State, divided by the national average hourly wage from Step 8 (see 84 FR 42305 and 42306) August 16, 2019). We stated that we believe that, in the absence of wage data for an urban labor market area, it is reasonable to use a statewide urban average, which is based on actual, acceptable wage data of hospitals in that State, rather than impute some other type of value using a different methodology. For calculation of the proposed FY 2021 wage index, we note there is one urban CBSA for which we do not have IPPS hospital wage data. In Table 3 (which is available via the internet on the CMS website) which contains the proposed area wage indexes, we include a footnote to indicate to which CBSAs this policy applies. These CBSAs' wage indexes would be equal to total urban salaries plus wage-related costs (from Step 5) in the respective State, divided by the total urban hours (from Step 4) in the respective State, divided by the national average hourly wage (from Step 8) (see 84 FR 42305 and 42306) August 16, 2019). Under this step, we also apply our policy with regard to how dollar amounts, hours, and other numerical values in the wage index calculations are rounded, as discussed in this section of this rule.

We refer readers to section II. of the Appendix of the proposed rule for the policy regarding rural areas that do not have IPPS hospitals.

Step 11.—Section 4410 of Public Law 105–33 provides that, for discharges on or after October 1, 1997, 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. The areas affected by this provision are identified in Table 2 listed in section VI. of the Addendum to the proposed rule and available via the internet on the CMS website.

Following is our policy with regard to rounding of the wage data (dollar amounts, hours, and other numerical values) in the calculation of the unadjusted and adjusted wage index, as finalized in the FY 2020 IPPS/LTCH final rule (84 FR 42306; August 16, 2019). For data that we consider to be ''raw data,'' such as the cost report data on Worksheets S–3, Parts II and III, and the occupational mix survey data, we use such data ''as is,'' and do not round any of the individual line items or fields. However, for any dollar amounts within the wage index calculations, including any type of summed wage amount, average hourly wages, and the national average hourly wage (both the unadjusted and adjusted for occupational mix), we round the dollar amounts to 2 decimals. For any hour amounts within the wage index calculations, we round such hour amounts to the nearest whole number. For any numbers not expressed as dollars or hours within the wage index calculations, which could include ratios, percentages, or inflation factors, we round such numbers to 5 decimals. However, we continue rounding the actual unadjusted and adjusted wage indexes to 4 decimals, as we have done historically.

As discussed in the FY 2012 IPPS/LTCH PPS final rule, in ''Step 5,'' for each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2016, through April 15, 2018, for private industry hospital workers from the BLS' Compensation and Working Conditions. We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we are not proposing any changes to the usage of the ECI for FY 2021. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated in the following table.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment Factor
10/14/2016	11/15/2016	1.02755
11/14/2016	12/15/2016	1.02560
12/14/2016	01/15/2017	1.02370
01/14/2017	02/15/2017	1.02180
02/14/2017	03/15/2017	1.01989
03/14/2017	04/15/2017	1.01803
04/14/2017	05/15/2017	1.01628
05/14/2017	06/15/2017	1.01465
06/14/2017	07/15/2017	1.01306
07/14/2017	08/15/2017	1.01145
08/14/2017	09/15/2017	1.00984
09/14/2017	10/15/2017	1.00822
10/14/2017	11/15/2017	1.00661
11/14/2017	12/15/2017	1.00503
12/14/2017	01/15/2018	1.00341
01/14/2018	02/15/2018	1.00174
02/14/2018	03/15/2018	1.00000
03/14/2018	04/15/2018	0.99814

For example, the midpoint of a cost reporting period beginning January 1, 2017, and ending December 31, 2017, is June 30, 2017. An adjustment factor of 1.01306 was applied to the wages of a hospital with such a cost reporting period.

Previously, we also would provide a Puerto Rico overall average hourly wage. As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915), prior to January 1, 2017, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we calculated a Puerto Rico specific wage index that was applied to the labor-related share of the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. As we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915 through 56916), because Puerto Rico hospitals are no longer paid with a Puerto Rico specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act, as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need to calculate a Puerto Rico specific average hourly wage and wage index. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national average hourly wage (unadjusted for occupational mix) and the national wage index, which is applied to the national labor-related share of the national standardized amount. Therefore, for FY 2021, there is no Puerto Rico-specific overall average hourly wage or wage index. Based on the previously described methodology, the proposed unadjusted national average hourly wage is the following:

Proposed FY 2021 Unadjusted National Average Hourly Wage	$45.11

E. Proposed Occupational Mix Adjustment to the FY 2021 Wage Index

As stated earlier, section 1886(d)(3)(E) of the Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

1. Use of 2016 Medicare Wage Index Occupational Mix Survey for the FY 2019, FY 2020, and FY 2021 Wage Indexes

Section 304(c) of the Consolidated Appropriations Act, 2001 (Pub. L. 106–554) amended section 1886(d)(3)(E) of the Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. As discussed in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19903) and final rule (82 FR 38137), we collected data in 2016 to

compute the occupational mix adjustment for the FY 2019, FY 2020, and FY 2021 wage indexes.

The FY 2021 occupational mix adjustment is based on the calendar year (CY) 2016 survey. Hospitals were required to submit their completed 2016 surveys (Form CMS–10079, OMB number 0938–0907, expiration date September 31, 2022) to their MACs by July 3, 2017. The preliminary, unaudited CY 2016 survey data were posted on the CMS website on July 12, 2017. As with the Worksheet S–3, Parts II and III cost report wage data, as part of the FY 2021 desk review process, the MACs revised or verified data elements in hospitals' occupational mix surveys that resulted in certain edit failures.

2. Deadline for Submitting the 2019 Medicare Wage Index Occupational Mix Survey for Use Beginning With the FY 2022 Wage Index

A new measurement of occupational mix is required for FY 2022. The FY 2022 occupational mix adjustment will be based on a new calendar year (CY) 2019 survey. The CY 2019 survey (CMS Form CMS–10079, OMB number 0938–0907, expiration date September 31, 2022) received OMB approval on October 18, 2019. The final CY 2019 Occupational Mix Survey Hospital Reporting Form is available on the CMS website at: *https://www.cms.gov/medicaremedicare-fee-service-paymentacuteinpatientppswage-index-files/2019-occupational-mix-survey-hospital-reporting-form-cms-10079-wage-index-beginning-fy-2022*. Hospitals were required to submit their completed 2019 surveys to their MACs (not directly to CMS), on the Excel hospital reporting form, by July 1, 2020 via email attachment or overnight delivery. CMS is granting an extension until August 3, 2020 for hospitals nationwide that may be unable to meet the July 1, 2020 deadline amidst the Novel Coronavirus Disease (COVID–19) national emergency. Hospitals should please see the CMS website at the previously mentioned link for information on this extension. As with the Worksheet S–3, Parts II and III cost report wage data, as part of the FY 2022 desk review process, the MACs will revise or verify data elements in hospitals' occupational mix surveys that result in certain edit failures.

3. Calculation of the Occupational Mix Adjustment for FY 2021

For FY 2021, we are proposing to calculate the occupational mix adjustment factor using the same methodology that we have used since the FY 2012 wage index (76 FR 51582 through 51586) and to apply the occupational mix adjustment to 100 percent of the FY 2021 wage index. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42308), we modified our methodology with regard to how dollar amounts, hours, and other numerical values in the unadjusted and adjusted wage index calculation are rounded, in order to ensure consistency in the calculation. According to the policy finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42308 and 42309), for data that we consider to be ''raw data,'' such as the cost report data on Worksheets S–3, Parts II and III, and the occupational mix survey data, we continue to use these data ''as is'', and not round any of the individual line items or fields. However, for any dollar amounts within the wage index calculations, including any type of summed wage amount, average hourly wages, and the national average hourly wage (both the unadjusted and adjusted for occupational mix), we round such dollar amounts to 2 decimals. We round any hour amounts within the wage index calculations to the nearest whole number. We round any numbers not expressed as dollars or hours in the wage index calculations, which could include ratios, percentages, or inflation factors, to 5 decimals. However, we continue rounding the actual unadjusted and adjusted wage indexes to 4 decimals, as we have done historically.

Similar to the method we use for the calculation of the wage index without occupational mix, salaries and hours for a multicampus hospital are allotted among the different labor market areas where its campuses are located. Table 2 associated with this proposed rule (which is available via the internet on the CMS website), which contains the proposed FY 2021 occupational mix adjusted wage index, includes separate wage data for the campuses of multicampus hospitals. We refer readers to section III.C. of the preamble of this proposed rule for a chart listing the multicampus hospitals and the FTE percentages used to allot their occupational mix data.

Because the statute requires that the Secretary measure the earnings and paid hours of employment by occupational category not less than once every 3 years, all hospitals that are subject to payments under the IPPS, or any hospital that would be subject to the IPPS if not granted a waiver, must complete the occupational mix survey, unless the hospital has no associated cost report wage data that are included in the FY 2021 wage index. For the proposed FY 2021 wage index, we are using the Worksheet S–3, Parts II and III wage data of 3,196 hospitals, and we are using the occupational mix surveys of 3,113 hospitals for which we also have Worksheet S–3 wage data, which represented a ''response'' rate of 97 percent (3,113/3,196). For the proposed FY 2021 wage index, we are applying proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586). As a result of applying this methodology, the proposed FY 2021 occupational mix adjusted national average hourly wage is the following:

Proposed FY 2021 Occupational Mix Adjusted National Average Hourly Wage	$45.07

F. Analysis and Implementation of the Proposed Occupational Mix Adjustment and the Proposed FY 2021 Occupational Mix Adjusted Wage Index

As discussed in section III.E. of the preamble of this proposed rule, for FY 2021, we are proposing to apply the occupational mix adjustment to 100 percent of the FY 2021 wage index. We calculated the occupational mix adjustment using data from the 2016 occupational mix survey data, using the methodology described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582 through 51586).

The proposed FY 2021 national average hourly wages for each occupational mix nursing subcategory as calculated in Step 2 of the occupational mix calculation are as follows.

Occupational Mix Nursing Subcategory	Average Hourly Wage
National RN	$41.60
National LPN and Surgical Technician	$24.67
National Nurse Aide, Orderly, and Attendant	$16.93
National Medical Assistant	$18.20
National Nurse Category	$34.96

The proposed national average hourly wage for the entire nurse category is computed in Step 5 of the occupational mix calculation. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of greater than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of less than 1.0. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of less than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of greater than 1.0.

Based on the 2016 occupational mix survey data, we determined (in Step 7 of the occupational mix calculation) that the national percentage of hospital employees in the nurse category is 42 percent, and the national percentage of hospital employees in the all other occupations category is 58 percent. At the CBSA level, the percentage of hospital employees in the nurse category ranged from a low of 27 percent in one CBSA to a high of 82 percent in another CBSA.

We compared the proposed FY 2021 occupational mix adjusted wage indexes for each CBSA to the proposed unadjusted wage indexes for each CBSA. Applying the proposed occupational mix adjustment to the wage data resulted in the following:

Comparison of the FY 2021 Proposed Occupational Mix Adjusted Wage Indexes to the Proposed Unadjusted Wage Indexes by CBSA	
Number of Urban Areas Wage Index Increasing	238 (57.8%)
Number of Rural Areas Wage Index Increasing	21 (44.7%)
Number of Urban Areas Wage Index Increasing by Greater Than or Equal to 1 Percent But Less Than 5 Percent	114 (27.7 %)
Number of Urban Areas Wage Index Increasing by 5 percent or More	7 (1.7 %)
Number of Rural Areas Wage Index Increasing by Greater Than or Equal to 1 Percent But Less Than 5 percent	9 (19.1%)
Number of Rural Areas Wage Index Increasing by 5 Percent or More	0 (0 %)
Number of Urban Areas Wage Index Decreasing	173 (42 %)
Number of Rural Areas Wage Index Decreasing	26 (55.3 %)
Number of Urban Areas Wage Index Decreasing by Greater Than or Equal to 1 Percent But Less Than 5 percent	76 (18.4 %)
Number of Urban Areas Wage Index Decreasing by 5 Percent or More	2 (0.5 %)
Number of Rural Areas Wage Index Decreasing by Greater Than or Equal to 1 Percent But Less than 5 Percent	8 (17 %)
Number of Rural Areas Wage Index Decreasing by 5 Percent or More	0 (0 %)
Largest Positive Impact for an Urban Area	6.44 %
Largest Positive Impact for a Rural Area	3.87 %
Largest Negative Impact for an Urban Area	5.97 %
Largest Negative Impact for a Rural Area	1.67 %
Urban Areas Unchanged by Application of the Occupational Mix Adjustment	1
Rural Areas Unchanged by Application of the Occupational Mix Adjustment	0

These results indicate that a larger percentage of urban areas (57.8 percent) would benefit from the occupational mix adjustment than would rural areas (44.7 percent).

G. Proposed Application of the Rural Floor, Proposed Application of the State Frontier Floor, and Continuation of the Low Wage Index Hospital Policy

1. Proposed Rural Floor

Section 4410(a) of Public Law 105–33 provides that, for discharges on or after October 1, 1997, 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 provision is referred to as the ''rural floor''. Section 3141 of Public

Law 111–148 also requires that a national budget neutrality adjustment be applied in implementing the rural floor. Based on the FY 2021 wage index associated with this proposed rule (which is available via the internet on the CMS website) and based on the calculation of the rural floor without the wage data of hospitals that have reclassified as rural under § 412.103, we estimate that 255 hospitals would receive an increase in their FY 2021 wage index due to the application of the rural floor.

2. Proposed State Frontier Floor for FY 2021

Section 10324 of Public Law 111–148 requires that hospitals in frontier States cannot be assigned a wage index of less than 1.0000. (We refer readers to the regulations at 42 CFR 412.64(m) and to a discussion of the implementation of this provision in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 through 50161).) In this FY 2021 IPPS/LTCH PPS proposed rule, we are not proposing any changes to the frontier floor policy for FY 2021. In this proposed rule, 45 hospitals would receive the frontier floor value of 1.0000 for their FY 2021 wage index. These hospitals are located in Montana, North Dakota, South Dakota, and Wyoming. We note that while Nevada meets the criteria of a frontier State, all hospitals within the State currently receive a wage index value greater than 1.0000.

The areas affected by the proposed rural and frontier floor policies for the proposed FY 2021 wage index are identified in Table 2 associated with this proposed rule, which is available via the internet on the CMS website.

3. Continuation of the Low Wage Index Hospital Policy

To help mitigate wage index disparities, including those resulting from the inclusion of hospitals with rural reclassifications under 42 CFR 412.103 in the rural floor, in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42325 through 42339), we finalized policies to reduce the disparity between high and low wage index hospitals by increasing the wage index values for certain hospitals with low wage index values and doing so in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals, as well as by changing the calculation of the rural floor. We also provided for a transition in FY 2020 for hospitals experiencing significant decreases in their wage index values as compared to their final FY 2019 wage index, and made these changes in a budget neutral manner.

We increase the wage index for hospitals with a wage index value below the 25th percentile wage index value for a fiscal year by half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals. We stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42326 through 42328) that this policy will be effective for at least 4 years, beginning in FY 2020, in order to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation. Therefore, this policy will continue in FY 2021. Based on the data for this proposed rule, for FY 2021, the 25th percentile wage index value across all hospitals would be 0.8420. In order to offset the estimated increase in IPPS payments to hospitals with wage index values below the 25th percentile wage index value, we are proposing to apply the budget neutrality adjustment in the same manner as we applied it in FY 2020, as a uniform budget neutrality factor applied to the standardized amount.

In addition, in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336), we removed urban to rural reclassifications from the calculation of the rural floor to prevent inappropriate payment increases under the rural floor due to rural reclassifications, such that, beginning in FY 2020, the rural floor is calculated without including the wage data of hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act (as implemented in the regulations at § 412.103). Also, for the purposes of applying the provisions of section 1886(d)(8)(C)(iii) of the Act, effective beginning in FY 2020, we remove the data of hospitals reclassified from urban to rural under section 1886(d)(8)(E) of the Act (as implemented in the regulations at § 412.103) from the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii). As previously mentioned in section III.G.1. of this proposed rule, the rural floor for this FY 2021 proposed rule is calculated without the wage data of hospitals that have reclassified as rural under § 412.103.

Lastly, for FY 2020, we placed a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in FY 2019 (84 FR 42336 through 42338). We applied a budget neutrality adjustment to the standardized amount so that this transition policy was implemented in a budget neutral manner. We clarified in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42337 through 42338) that this 5-percent cap on wage index decreases applied to all hospitals that have any decrease in their wage indexes, regardless of the circumstance causing the decline, so that a hospital's final wage index for FY 2020 will not be less than 95 percent of its final wage index for FY 2019. In light of the recent OMB updates described in section III.B.2. of this proposed rule, for FY 2021 we are proposing to again cap any decreases in the wage index at 5 percent so that a hospital's final wage index for FY 2021 will not be less than 95 percent of its final wage index for FY 2020, and to apply a budget neutrality adjustment for this proposed transition policy in the same manner as in FY 2020. As previously mentioned, on September 14, 2018, OMB issued OMB Bulletin No. 18–04 which established revised delineations. Consistent with our past practice of implementing transition policies to help mitigate negative impacts on hospitals of certain wage index proposals, due to the revised OMB delineations, for FY 2021 we are proposing to again provide for a transition of a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index from the prior fiscal year which would be FY 2020. We refer readers to section III.B.2.c. of the preamble of this proposed rule for a complete discussion of the proposed wage index transition policy.

H. Proposed FY 2021 Wage Index Tables

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49498 and 49807 through 49808), we finalized a proposal to streamline and consolidate the wage index tables associated with the IPPS proposed and final rules for FY 2016 and subsequent fiscal years. Prior to FY 2016, the wage index tables had consisted of 12 tables (Tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4E, 4F, 4J, 9A, and 9C) that were made available via the internet on the CMS website. Effective beginning FY 2016, with the exception of Table 4E, we streamlined and consolidated 11 tables (Tables 2, 3A, 3B, 4A, 4B, 4C, 4D, 4F, 4J, 9A, and 9C) into 2 tables (Tables 2 and 3). As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41380), beginning with FY 2019, we added Table 4 which is titled and includes a ''List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act'' for the relevant fiscal year. We refer readers to section VI. of the Addendum to this proposed rule for a discussion of the proposed wage index tables for FY 2021.

I. Proposed Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications

1. General Policies and Effects of Reclassification and Redesignation

Under section 1886(d)(10) of the Act, the Medicare Geographic Classification Review Board (MGCRB) considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. Hospitals must apply to the MGCRB to reclassify not later than 13 months prior to the start of the fiscal year for which reclassification is sought (usually by September 1). Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics similar to hospitals located in that area. The MGCRB issues its decisions by the end of February for reclassifications that become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in 42 CFR 412.230 through 412.280. (We refer readers to a discussion in the FY 2002 IPPS final rule (66 FR 39874 and 39875) regarding how the MGCRB defines mileage for purposes of the proximity requirements.) The general policies for reclassifications and redesignations and the policies for the effects of hospitals' reclassifications and redesignations on the wage index are discussed in the FY 2012 IPPS/LTCH PPS final rule for the FY 2012 final wage index (76 FR 51595 and 51596). We note that rural hospitals reclassifying under the MGCRB to another state's rural area are not eligible for the rural floor, because the rural floor may apply to urban, not rural, hospitals.

In addition, in the FY 2012 IPPS/LTCH PPS final rule, we discussed the effects on the wage index of urban hospitals reclassifying to rural areas under 42 CFR 412.103. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336), we finalized a policy to exclude the wage data of urban hospitals reclassifying to rural areas under 42 CFR 412.103 from the calculation of the rural floor. Hospitals that are geographically located in States without any rural areas are ineligible to apply for rural reclassification in accordance with the provisions of 42 CFR 412.103.

On April 21, 2016, we published an interim final rule with comment period (IFC) in the **Federal Register** (81 FR 23428 through 23438) that included provisions amending our regulations to allow hospitals nationwide to have simultaneous § 412.103 and MGCRB reclassifications. For reclassifications effective beginning FY 2018, a hospital may acquire rural status under § 412.103 and subsequently apply for a reclassification under the MGCRB using distance and average hourly wage criteria designated for rural hospitals. In addition, we provided that a hospital that has an active MGCRB reclassification and is then approved for redesignation under § 412.103 will not lose its MGCRB reclassification; such a hospital receives a reclassified urban wage index during the years of its active MGCRB reclassification and is still considered rural under section 1886(d) of the Act and for other purposes.

We discussed that when there is both a § 412.103 redesignation and an MGCRB reclassification, the MGCRB reclassification controls for wage index calculation and payment purposes. We exclude hospitals with § 412.103 redesignations from the calculation of the reclassified rural wage index if they also have an active MGCRB reclassification to another area. That is, if an application for urban reclassification through the MGCRB is approved, and is not withdrawn or terminated by the hospital within the established timelines, we consider the hospital's geographic CBSA and the urban CBSA to which the hospital is reclassified under the MGCRB for the wage index calculation. We refer readers to the April 21, 2016 IFC (81 FR 23428 through 23438) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56922 through 56930) for a full discussion of the effect of simultaneous reclassifications under both the § 412.103 and the MGCRB processes on wage index calculations. For a discussion on the effects of reclassifications under § 412.103 on the rural area wage index and the calculation of the rural floor, we refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336).

2. MGCRB Reclassification and Redesignation Issues for FY 2021

a. FY 2021 Reclassification Application Requirements and Approvals

As previously stated, under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. The specific procedures and rules that apply to the geographic reclassification process are outlined in regulations under 42 CFR 412.230 through 412.280. At the time this proposed rule was constructed, the MGCRB had completed its review of FY 2021 reclassification requests. Based on such reviews, there are 435 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2021. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2021, hospitals reclassified beginning in FY 2019 or FY 2020 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications for the remainder of their 3-year period. There were 244 hospitals approved for wage index reclassifications in FY 2019 that will continue for FY 2021, and 279 hospitals approved for wage index reclassifications in FY 2020 that will continue for FY 2021. Of all the hospitals approved for reclassification for FY 2019, FY 2020, and FY 2021, based upon the review at the time of this proposed rule, 957 hospitals are in a MGCRB reclassification status for FY 2021 (with 101 of these hospitals reclassified back to their geographic location).

Under the regulations at 42 CFR 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications if the request for withdrawal is received by the MGCRB any time before the MGCRB issues a decision on the application, or after the MGCRB issues a decision, provided the request for withdrawal is received by the MGCRB within 45 days of the date that CMS' annual notice of proposed rulemaking is issued in the **Federal Register** concerning changes to the inpatient hospital prospective payment system and proposed payment rates for the fiscal year for which the application has been filed. For information about withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, we refer readers to § 412.273, as well as the FY 2002 IPPS final rule (66 FR 39887 through 39888) and the FY 2003 IPPS final rule (67 FR 50065 through 50066). Additional discussion on withdrawals and terminations, and clarifications regarding reinstating reclassifications and ''fallback'' reclassifications were included in the FY 2008 IPPS final rule (72 FR 47333) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38148 through 38150).

b. Hospitals With One or Two Years of Wage Data Seeking MGCRB Reclassification

We are proposing to modify the regulation at § 412.230(d)(2)(ii)(A) to clarify that a hospital may qualify for an individual wage index reclassification by the MGCRB under § 412.230 to another labor market area if the hospital only has 1 or 2 years of wage data. Section 412.230(d)(2)(ii)(A) provides that, for hospital-specific wage data, a

hospital must provide a weighted 3-year average of its average hourly wages using data from the CMS hospital wage survey used to construct the wage index. We note that in certain circumstances, such as that of a new hospital, a hospital may not have 3 years of published wage data within the applicable 3-year average hourly wage period used by the MGCRB. In such cases, it has been CMS's longstanding policy that a hospital must accumulate at least 1 year of wage data within the applicable 3-year average hourly wage period used by the MGCRB, in order to apply for individual reclassification. We are concerned that this policy may not be clear in the current regulation text at § 412.230(d)(2)(ii)(A), and we are now proposing to revise § 412.230(d)(2)(ii)(A) to clarify this. For hospitals that have accumulated fewer than 3 years of wage data within the applicable 3-year average hourly wage period used by the MGCRB, the appropriate hospital-specific wage data to be used by an applicant under § 412.230(d) is either the single year of published wage data (if the hospital has accumulated just 1 year of wage data), or, if applicable, the weighted average of its 2 years of wage data within the 3-year period reviewed by the MGCRB. Although § 412.230(d)(2)(iv) reflects this longstanding policy as it pertains to new providers, we note that this policy has not been limited to new providers. Section 412.230(d)(2)(iv) specifies that if a new owner does not accept assignment of the hospital's provider agreement, the hospital is considered a new provider with a new provider number, and the wage data associated with the previous hospital's provider number cannot be used to calculate the new hospital's 3-year average hourly wage. Section 412.230(d)(2)(iv) further states that, in this case, the new hospital would be eligible to apply for an individual MGCRB reclassification after accumulating at least 1 year of wage data (we refer readers to the FY 2003 IPPS/LTCH final rule (67 FR 50066) for further discussion of this policy). As previously noted, however, we have not limited this wage data policy to new providers, and thus we are proposing to revise § 412.230(d)(2)(ii)(A) to clarify this. Specifically, we are proposing to reformat § 412.230(d)(2)(ii)(A) so that it consists of two paragraphs (paragraphs (d)(2)(ii)(A)(*1*) and (*2*)), and to include new language in new of § 412.230(d)(2)(ii)(A)(*2*) stating that once a hospital has accumulated at least 1 year of wage data in the applicable 3-year average hourly wage period used by the MGCRB, the hospital is eligible to apply for reclassification based on those data Consistent with our current policy, hospitals without wage data or that have accumulated less than 1 year of wage data would not be eligible for individual wage index reclassification.

c. Effects of Implementation of Revised OMB Labor Market Area Delineations on Reclassified Hospitals

(1) Assignment Policy for Hospitals Reclassified to CBSAs Where One or More Counties Move to a New or Different Urban CBSA

Because hospitals that have been reclassified beginning in FY 2019, 2020, or 2021 were reclassified based on the current labor market delineations, if we adopt the revised OMB delineations based on the OMB Bulletin No. 18–04 beginning in FY 2021, the areas to which they have been reclassified, or the areas where they are located, may change. Under the revised OMB delineations, some existing CBSAs would be reconfigured. Hospitals with current reclassifications are encouraged to verify area wage indexes on Table 2 in the appendix of proposed rule, and confirm that the areas to which they have been reclassified for FY 2021 would continue to provide a higher wage index than their geographic area wage index. Hospitals may withdraw or terminate their FY 2021 reclassifications by contacting the MGCRB within 45 days from the date this proposed rule is issued in the **Federal Register** (§ 412.273(c)).

In some cases, adopting the revised OMB delineations would result in counties splitting apart from CBSAs to form new CBSAs, or counties shifting from one CBSA designation to another CBSA. Reclassifications granted under section 1886(d)(10) of the Act are effective for 3 fiscal years so that a hospital or county group of hospitals would be assigned a wage index based upon the wage data of hospitals in a nearby labor market area for a 3-year period. If CBSAs are split apart, or if counties shift from one CBSA to another under the revised OMB delineations, we must determine which reclassified area to assign to the hospital for the remainder of a hospital's 3-year reclassification period if the area to which the hospital reclassified split or had counties shift to another new or modified urban CBSA.

Consistent with the policy CMS implemented in the FY 2005 IPPS final rule (69 FR 49054 through 49056) and in the FY 2015 IPPS final rule (79 FR 49973 through 49977), for FY 2021, if a CBSA would be reconfigured due to adoption of the revised OMB delineations and it would not be possible for the reclassification to continue seamlessly to the reconfigured CBSA, we believe it would be appropriate for us to determine the best alternative location to reassign current reclassifications for the remaining 3 years. Therefore, to maintain the integrity of a hospital's 3-year reclassification period, we are proposing that current geographic reclassifications (applications approved effective for FY 2019, FY 2020, or FY 2021) that would be affected by CBSAs that are split apart or counties that shift to another CBSA under the revised OMB delineations, would ultimately be assigned to a CBSA under the revised OMB delineations that contains at least one county from the reclassified CBSA under the current FY 2020 definitions, and would be generally consistent with rules that govern geographic reclassification. That is, consistent with the policy finalized in FY 2015 (79 FR 49973), we are proposing a policy that affected reclassified hospitals be assigned to a CBSA that would contain the most proximate county that—(1) is located outside of the hospital's proposed FY 2021 geographic labor market area, and (2) is part of the original FY 2020 CBSA to which the hospital is reclassified. (Please note, in the next section, we are making a minor modification to this proposed assignment policy for certain hospitals currently reclassified to their current geographic CBSA (that is, as discussed later in this section, we would not require these reclassifications to be assigned to a CBSA outside the hospital's proposed FY 2021 geographic labor market area)). We believe that assigning reclassifications to the CBSA that contains the nearest county that meets the aforementioned criteria satisfies the statutory requirement at section 1886(d)(10)(v) of the Act by maintaining reclassification status for a period of 3 fiscal years, while generally respecting the longstanding principle of geographic proximity in the labor market reclassification process. For county group reclassifications, we would follow our proposed policy, as previously discussed, except that, for county group reclassifications, we are proposing to reassign hospitals in a county group reclassification to the CBSA under the revised OMB delineations that contains the county to which the majority of hospitals in the group reclassification are geographically closest. We are also proposing to allow such hospitals, or county groups of hospitals, to submit a request to the *wageindex@cms.hhs.gov* mailbox for reassignment to another CBSA that

would contain a county that is part of the current FY 2020 CBSA to which it is reclassified if the hospital or county group of hospitals can demonstrate compliance with applicable reclassification proximity rules, as described later in this section.

We recognize that the proposed reclassification reassignment policy, as previously described, for hospitals that are reclassified to CBSAs that would split apart or to counties that would shift to another CBSA under the revised OMB delineations may result in the reassignment of the hospital for the remainder of its 3-year reclassification period to a CBSA having a lower wage index than the wage index that would have been assigned for the reclassified hospital in the absence of the proposed adoption of the revised OMB delineations. Therefore, as discussed in section III.B.2.e. of the preamble of this proposed rule, as a transition, we are proposing to continue to apply for FY 2021 a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index for the prior fiscal year. In other words, we would apply a 5 percent cap in FY 2021 on any decrease in a hospital's wage index compared to its final wage index for FY 2020. We believe that this proposed transitional wage index would mitigate significant negative payment impacts for FY 2021, and would afford hospitals adequate time to fully assess any additional reclassification options available to them.

We note that if the CBSA to which a hospital is reclassified experiences only a change in name and/or number, (in other words, a county (or county equivalent) did not move to a new or different CBSA), we considered the CBSA, and associated reclassifications, to remain unchanged. For example, any hospital reclassified to current CBSA 19380 (Dayton, OH), 39140 (Prescott, AZ) or 43524 (Silver Spring-Frederick-Rockville, MD) would have its reclassification transferred to the proposed equivalent CBSA 19430 (Dayton-Kettering, OH), 39150 (Prescott Valley-Prescott, AZ), and 23224 (Frederick-Gaithersburg-Rockville, MD), respectively.

The following Table 1 provides a list of current FY 2020 CBSAs (column 1) where one or more counties would be relocated to a new or different urban CBSA. Hospitals with FY 2020 MGCRB reclassifications into the CBSAs in column 1 would be subject to the proposed reclassification assignment policy. The third column of ''eligible'' CBSAs lists all proposed revised CBSAs that contain at least one county that is part of the current FY 2020 CBSA (in column 1).

Current CBSA	Current CBSA Name	Eligible Assignment CBSAs
16974	Chicago-Naperville-Arlington Heights, IL	16984, 20994
20524	Dutchess County-Putnam County, NY	39100, 35614
26580	Huntington-Ashland, WV-KY-OH	26580, 16620
28940	Knoxville, TN	28940, 34100
35084	Newark, NJ-PA	35084, 35154
35614	New York-Jersey City-White Plains, NY-NJ	35614, 35154, 39100
38660	Ponce, PR	38660, 49500

The following Table 2 lists all hospitals subject to our proposed reclassification assignment policy and where their reclassifications would be assigned for FY 2021 under this proposed policy. The table lists reclassifications that would be in effect for FY 2021 under our proposed policy, and included in Table 2 in the addendum of this proposed rule. The table also includes reclassifications (noted by an asterisk on the ''MGCRB Case Number'') that were approved in FY 2019 or FY 2020 and are superseded by a new FY 2021 reclassification. These prior year reclassifications, frequently referred to as ''fallback'' reclassifications, may become active if the subsequent FY 2021 reclassification is withdrawn. (Please note, the following table does not include hospitals currently reclassified to their ''home'' geographic area, which are discussed in the next section.

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Table 2. Hospitals Subject to Proposed Reclassification Assignment Policy

CCN	MGCRB Case	Current Approved CBSA	Proposed Assigned CBSA
07B033	20C0067*	35614	35614
140029	19G0188	16974	16984
140030	19G0188	16974	16984
140155	20G0271	16974	16984
140161	19C0122	16974	16984
140174	19G0188	16974	16984
140186	20G0271	16974	16984
140211	19G0188	16974	16984
140217	19G0188	16974	16984
140286	19G0189	16974	16984
150002	19G0186	16974	16984
150004	19G0186	16974	16984
150008	19G0186	16974	16984
150015	19C0182	16974	16984
150034	19G0186	16974	16984
150035	20C0214	16974	16984
150090	19G0186	16974	16984
150125	19G0186	16974	16984
150126	19G0186	16974	16984
150165	19G0186	16974	16984
150166	19G0186	16974	16984
180005	21C0002	26580	26580
180044	20C0328	26580	26580
180069	20C0076	26580	26580
180078	20C0164	26580	26580
310002	21G0336	35614	35614
310009	21G0336	35614	35614
310015	20G0138	35614	35614
310017	20G0138	35614	35614
310021	19G0047	35084	35084
310044	19G0047*	35084	35084
310044	21C0078	35614	35154
310050	20G0138	35614	35614
310051	19C0135	35614	35154
310054	21G0336	35614	35614
310060	21G0035	35084	35084
310076	21G0336	35614	35614
310083	21G0336	35614	35614
310092	19G0047	35084	35084
310096	21G0336	35614	35614
310110	19G0047	35084	35084
310115	21G0035	35084	35084
310119	21G0336	35614	35614

CCN	MGCRB Case	Current Approved CBSA	Proposed Assigned CBSA
330023	20G0265	35614	35614
330049	20G0265	35614	35614
330224	20C0127	20524	39100
33B234	20G0265	35614	35614
330386	19C0063	35614	39100
360008	20C0195	26580	26580
390027	21C0393	35614	35154
390049	19C0027	35084	35084
390133	19C0118	35084	35084
390162	21C0350	35084	35084
390201	21C0050	35084	35084
390258	21C0371	35084	35084
390270	19C0220	35084	35084
440056	20G0233	28940	28940
510022	19C0040	26580	26580
520059	21C0233	16974	16984
520096	19C0152*	16974	16984
520102	21C0234	16974	16984

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If a hospital that is subject to the proposed reclassification assignment policy discussed earlier in this section wishes to be reassigned to another eligible CBSA (that is, to a CBSA other than the CBSA to which their reclassification would be assigned under the proposed reclassification assignment policy and that contains at least one county from the CBSA to which they are reclassified for FY 2020) for which they meet the applicable proximity criteria may request reassignment within 45 days from the date the proposed rule is placed on display at the **Federal Register**. Hospitals must send a request to *WageIndex@cms.hhs.gov* and provide documentation establishing that they meet the requisite proximity criteria for reassignment to an alternate CBSA that contains one or more counties from the CBSA to which they are currently reclassified for FY 2020. We believe this option of allowing these hospitals to submit a request to CMS would provide hospitals with greater flexibility with respect to their reclassification reassignment, while ensuring that the proximity requirements are met. We believe that where the proximity requirements are met, the reclassified wage index would be consistent with the labor market area to which the hospitals were originally approved for reclassification. Thus, a hospital that is subject to our proposed reclassification assignment policy may request to reassign an individual reclassification to any CBSA that contains a county from the CBSA to which it is currently reclassified for FY 2020. However, to be reassigned to an area that is not the most proximate to the hospital, we believe it is necessary that the hospital demonstrates that it complies with the applicable proximity criteria. If a hospital cannot demonstrate proximity to a different eligible CBSA, the hospital would not be considered for reclassification to that labor market area, and the reclassification would remain with the CBSA assigned under the reclassification assignment policy proposed earlier in this section. In the case of a county group reclassification, all requests for reassignment must include all active hospitals (that is, excluding any hospital that has since closed or converted to a different provider type) included on the original MGCRB reclassification application. County groups must also demonstrate that they meet the appropriate proximity requirements, including, for rural county groups, being adjacent to the MSA to which they seek redesignation (§ 412.232(a)(1)(ii)), and for urban county groups, being in the same Combined Statistical Area or Core-Based Statistical Area as the urban area to which they seek redesignation (§ 412.234(a)(3)(iv).

All hospital requests for reassignment should contain the hospital's name, address, CCN, and point of contact information. All requests must be sent to *WageIndex@cms.hhs.gov*. Changes to a hospital's CBSA assignment on the basis of a hospital's disagreement with our determination of closest county, or on the basis of being granted a reassignment due to meeting applicable proximity criteria to an alternate eligible CBSA will be announced in the FY 2021 IPPS/LTCH PPS final rule. Finally, we note that MGCRB case 21C0026 was denied by the MGCRB for reclassification to CBSA 35614. The hospital (CCN 310064) has appealed this decision to the Office of the Administrator. The result of this appeal was not available in time to include in this proposed rule. If this decision is overturned in favor of the hospital, based on our analysis, this reclassification would be assigned to CBSA 35154 under our proposed reclassification assignment policy.

(2) Proposed Treatment for Hospitals Reclassified to Their Geographic CBSA

Under the previous assignment policy implemented in FY 2015 IPPS/LTCH final rule, a hospital reclassified to a CBSA that had one or more counties moved to a new of different urban CBSA was required to be assigned a new or revised CBSA that is *different* than its proposed geographic CBSA (79 FR 49974 and 49975). We adopted the policy that the assigned CBSA must be *different* than the hospital's geographic area to ensure that a hospital that qualified for reclassification to a different area continued to be eligible to receive a different wage index than its home area. We continue to believe this is the appropriate policy for hospitals that originally reclassified to a different area. However, as noted in the prior section, for hospitals currently reclassified to their current geographic CBSA, we are proposing to implement a reclassification assignment policy consistent with the policy implemented

in FY 2015, with a minor modification in that we would not require these reclassifications to be assigned to a CBSA outside the hospital's proposed FY 2021 geographic labor market area. Since the FY 2015 IPPS/LTCH final rule was issued, CMS has allowed, under certain circumstances, a hospital to seek an MGCRB wage index reclassification to its own geographic CBSA. We refer readers to a comment response in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56925) discussing such a scenario. In these cases, the hospitals are assigned the same wage index value as other hospitals located in its geographic labor market area, not the wage index assigned to hospitals reclassified to that area. We are proposing to assign ''home area'' reclassifications to the hospital's proposed geographic CBSA. The assigned ''home area'' reclassification CBSA may be different from previous years if the hospital is located in a county that was relocated to a new or different urban CBSA. The following table lists hospitals with current ''home area'' reclassifications to one of the seven CBSAs (identified in Table 1 earlier in this section) where one or more counties would move to a new or different urban CBSA, and each hospital's proposed assigned CBSA (column 4).

Table 3. Home Area Reclassifications Subject to Proposed Assignment Policy

CCN	MGCRB Case	Current Approved CBSA	Proposed Assigned CBSA
140008	21C0243	16974	16984
140054	21C0246	16974	16984
140065	21C0304	16974	16984
140080	21C0305	16974	16984
140082	21C0373	16974	16984
140088	21C0187	16974	16984
140117	21C0306	16974	16984
140119	21C0126	16974	16984
140150	21C0116	16974	16984
140172	21C0096	16974	16984
140179	21C0287	16974	16984
140180	21C0308	16974	16984
140223	21C0236	16974	16984
140258	21C0309	16974	16984
140276	21C0245	16974	16984
140281	21C0075	16974	16984
140290	21C0310	16974	16984
330273	19G0250	35614	35614
440015	19C0206	28940	28940
440125	19C0276	28940	28940

We also note that in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49977), CMS terminated reclassifications when, as a result of adopting the revised OMB delineations, a hospital's geographic county was reassigned to the CBSA for which it was approved for MGCRB reclassification. At that time, ''home area'' reclassifications were not possible. However, since CMS now allows ''home area'' reclassifications, as discussed previously, we would consider this scenario to be a ''home area'' reclassification and we do not believe it is necessary to terminate these reclassifications as we did in FY 2015. We note that hospitals with a ''home area'' reclassification (or any other form of reclassification) are not eligible to receive an outmigration adjustment determined under section 1886(d)(13) of the Act. If such an adjustment is available, a hospital may wish to consider withdrawing or terminating its reclassification by contacting the MGCRB within 45 days of the date this proposed rule is issued in the **Federal Register** (§ 412.273(c)).

3. Redesignations Under Section 1886(d)(8)(B) of the Act

a. Lugar Status Determinations

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600), we adopted the policy that, beginning with FY 2012, an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS effective for the fiscal year in which the hospital receives the outmigration adjustment. In addition, in that rule, we adopted a minor

procedural change that would allow a Lugar hospital that qualifies for and accepts the out-migration adjustment (through written notification to CMS within 45 days from the publication of the proposed rule) to waive its urban status for the full 3-year period for which its out-migration adjustment is effective. By doing so, such a Lugar hospital would no longer be required during the second and third years of eligibility for the out-migration adjustment to advise us annually that it prefers to continue being treated as rural and receive the out-migration adjustment. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56930), we further clarified that if a hospital wishes to reinstate its urban status for any fiscal year within this 3-year period, it must send a request to CMS within 45 days of publication of the proposed rule for that particular fiscal year. We indicated that such reinstatement requests may be sent electronically to *wageindex@cms.hhs.gov*. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38147 through 38148), we finalized a policy revision to require a Lugar hospital that qualifies for and accepts the out-migration adjustment, or that no longer wishes to accept the out-migration adjustment and instead elects to return to its deemed urban status, to notify CMS within 45 days from the date of public display of the proposed rule at the Office of the Federal Register. These revised notification timeframes were effective beginning October 1, 2017. In addition, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38148), we clarified that both requests to waive and to reinstate ''Lugar'' status may be sent to *wageindex@cms.hhs.gov*. To ensure proper accounting, we request hospitals to include their CCN, and either ''waive Lugar'' or ''reinstate Lugar'', in the subject line of these requests.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42314 and 42315), we clarified that in circumstances where an eligible hospital elects to receive the outmigration adjustment within 45 days of the public display date of the proposed rule at the Office of the Federal Register in lieu of its Lugar wage index reclassification, and the county in which the hospital is located would no longer qualify for an out-migration adjustment when the final rule (or a subsequent correction notice) wage index calculations are completed, the hospital's request to accept the outmigration adjustment would be denied, and the hospital would be automatically assigned to its deemed urban status under section 1886(d)(8)(B) of the Act. We stated that final rule wage index values would be recalculated to reflect this reclassification, and in some instances, after taking into account this reclassification, the out-migration adjustment for the county in question could be restored in the final rule. However, as the hospital is assigned a Lugar reclassification under section 1886(d)(8)(B) of the Act, it would be ineligible to receive the county outmigration adjustment under section 1886(d)(13)(G) of the Act. Because the out-migration adjustment, once finalized, is locked for a 3-year period under section 1886(d)(13)(F) of the Act, the hospital would be eligible to accept its out-migration adjustment in either the second or third year.

b. Effects of Implementation of Revised OMB Labor Market Area Delineations on Redesignations Under Section 1886(d)(8)(B) of the Act

As discussed in section III.A.2. of the preamble of this proposed rule, CMS is proposing to update the CBSA labor market delineations to reflect the changes made in the September 14, 2018 OMB Bulletin 18–04. In that section, we proposed that 47 currently rural counties be added to new or existing urban CBSAs. Of those 47 counties, 23 are currently deemed urban under Section 1886(d)(8)(B) of the Act. Hospitals located in such a ''Lugar'' county, barring another form of wage index reclassification, are assigned the reclassified wage index of a designated urban CBSA. Section 1886(d)(8)(B) of the Act defines a deemed urban county as a ''rural county adjacent to one or more urban areas'' that meets certain commuting thresholds. Since we are proposing to modify the status of these 23 counties from rural to urban, they would no longer qualify as ''Lugar'' counties. Hospitals located within these counties would be considered geographically urban under the revised OMB delineations. The following table lists the counties that would no longer be deemed urban under section 1886(d)(8)(B) of the Act if we adopt the revised OMB delineations.

COUNTIES THAT WOULD NO LONGER BE DEEMED URBAN UNDER

1886(d)(8)(B) OF THE ACT DUE TO PROPOSED URBAN GEOGRAPHICAL STATUS

County Name	FIPSCD	Current "Lugar" CBSA	CBSA Name
LEVY	12075	23540	Gainesville, FL
TALBOT	13263	17980	Columbus, GA-AL
PARKE	18121	45460	Terre Haute, IN
WARREN	18171	29200	Lafayette-West Lafayette, IN
BOONE	19015	11180	Ames, IA
JASPER	19099	19780	Des Moines-West Des Moines, IA
ASSUMPTION	22007	12940	Baton Rouge, LA
FRANKLIN	25011	44140	Springfield, MA
IONIA	26067	24340	Grand Rapids-Kentwood, MI
SHIAWASSEE	26155	29620	Lansing-East Lansing, MI
STONE	28131	25060	Gulfport-Biloxi, MS
CAMDEN	37029	47260	Virginia Beach-Norfolk-Newport News, VA-NC
GRANVILLE	37077	20500	Durham-Chapel Hill, NC
HARNETT	37085	39580	Raleigh-Cary, NC
ADJUNTAS	72001	38660	Ponce, PR
LAS MARIAS	72083	32420	Mayagüez, PR
CLARENDON	45027	44940	Sumter, SC
HARRISON	48203	30980	Longview, TX
KING AND QUEEN	51097	40060	Richmond, VA
MADISON	51113	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV
SOUTHAMPTON	51175	47260	Virginia Beach-Norfolk-Newport News, VA-NC
JACKSON	54035	16620	Charleston, WV
MORGAN	54065	25180	Hagerstown-Martinsburg, MD-WV

We note that in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49973 through 49977), when we adopted large scale changes to the CBSA labor market delineations based on the new decennial census, we also re-evaluated the commuting data thresholds for all eligible rural counties in accordance with the methodology set forth in 1886(d)(8)(B). In FY 2015, the OMB bulletin we used to update the CBSA delineations was based on the results of the 2010 decennial census, and had broad ranging nationwide impacts. With some exceptions, notably the FY 2020 IPPS/LTCH final rule where we modified the CBSA assignment for some ''Lugar'' counties based on a revised interpretation of the statute (84 FR 42315 through 42318), it has been CMS's long-standing policy to only revise the list of qualifying counties in conjunction with the adoption of the large scale OMB delineation changes following the results of a decennial census. 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. Although we believe the transition wage index described in section III.B.2.e. of the preamble of this proposed rule would mitigate significant negative impacts on affected hospitals, and provide hospitals with adequate time to evaluate alternative wage index reclassification options, we are aware that several hospitals in counties that would be considered rural under the revised OMB delineations would qualify for ''Lugar'' status, were CMS to reevaluate the commuting data and new labor market delineations. We believe providing Lugar status to these hospitals, as appropriate, would further mitigate any significant negative impacts on affected hospitals. We are therefore proposing to reevaluate the ''Lugar'' status for all counties in FY 2021 using the same commuting data table used to evaluate

the list of ''Lugar'' counties when CMS adopted new OMB delineations in FY 2015 rulemaking. The data table is the ''2006–2010 5-Year American Community Survey Commuting Flows and Employment'' (available on OMB's website: *https://www.census.gov/data/tables/2010/demo/metro-micro/commuting-employment-2010.html*). Since we are using the same data tables, any difference in the list of qualifying counties would be solely due to the effects of the updated OMB delineations. We believe that making the proposed revisions to the qualifying counties using the updated OMB delineations but the same 2006–2010 commuting data tables used in the FY 2015 IPPS/LTCH PPS final rule trikes an appropriate balance between reserving comprehensive revisions to the list of qualifying counties to instances where we adopt large scale OMB delineation changes following a decennial census, and the desire to mitigate any significant negative impacts on hospitals of the proposed updated OMB delineations (which do contain a number of material changes). We are also proposing to use the same methodology discussed in the FY 2020 IPPS/LTCH final rule (84 FR 42315 through 42318) to assign the appropriate reclassified CBSA for hospitals in ''Lugar'' counties. That is, when assessing which CBSA to assign, we will sum the total number of workers that commute from the ''Lugar'' county to both ''central'' and ''outlying'' urban counties (rather than just ''central'' county commuters).

By applying the 2010 ACS commuting data to the updated OMB labor market delineations, we are proposing the following changes to the current ''Lugar'' county list. Most notably, based on this commuting data and the revised OMB delineations, all 34 urban counties that became rural under the revised OMB delineations would qualify as ''Lugar'' counties and all hospitals located within them would be designated as ''Lugar.'' This would affect 10 current hospitals located in those counties. Additionally, due to the change in designation of some urban counties from ''outlying'' to ''central'' status by OMB, we are proposing to add two current rural counties in NY as ''Lugar'' counties. Specifically, hospitals located in Columbia county, NY (FIPSCD 36021) would be deemed ''Lugar'' hospitals and reclassified to urban CBSA 10580 (Albany-Schenectady-Troy, NY) and hospitals located in Sullivan county, NY (FIPCD 36105) would be deemed ''Lugar'' hospitals and reclassified to urban CBSA 39100 (Poughkeepsie-Newburgh-Middletown, NY). However, we note all hospitals in these New York counties currently have MGCRB reclassifications in place for FY 2021, which would supersede these ''Lugar'' reclassifications. Finally, Calhoun County, TX (FIPSCD 48057) would no longer qualify as a ''Lugar'' county due to the fact it is no longer adjacent to CBSA 18580 (Corpus Christi, TX). We are proposing to remove Calhoun County from the list of ''Lugar'' counties. We note that there are no IPPS hospitals located in Calhoun County.

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RURAL COUNTIES CONTAINING HOSPITALS THAT WOULD BE REDESIGNATED AS URBAN UNDER SECTION 1886(d)(8)(B) OF THE ACT (based on proposed revised OMB delineations and 2010 census data)

Lugar County Name	State	FIPSCD	CBSA	CBSA Name
CHAMBERS	AL	01017	12220	Auburn-Opelika, AL
CHEROKEE	AL	01019	40660	Rome, GA
CLEBURNE	AL	01029	12060	Atlanta-Sandy Springs-Alpharetta, GA
MACON	AL	01087	12220	Auburn-Opelika, AL
TALLADEGA	AL	01121	13820	Birmingham-Hoover, AL
WALKER	AL	01127	13820	Birmingham-Hoover, AL
DENALI	AK	02068	21820	Fairbanks, AK
HOT SPRING	AR	05059	26300	Hot Springs, AR
LITCHFIELD	CT	09005	35300	New Haven-Milford, CT
BRADFORD	FL	12007	23540	Gainesville, FL
GULF	FL	12045	37460	Panama City, FL
WASHINGTON	FL	12133	37460	Panama City, FL
BAKER	GA	13007	10500	Albany, GA
CHATTOOGA	GA	13055	40660	Rome, GA
JACKSON	GA	13157	12060	Atlanta-Sandy Springs-Alpharetta, GA
LUMPKIN	GA	13187	12060	Atlanta-Sandy Springs-Alpharetta, GA
POLK	GA	13233	12060	Atlanta-Sandy Springs-Alpharetta, GA
PULASKI	GA	13235	47580	Warner Robins, GA
KALAWAO	HI	15005	36260	Kahului-Wailuku-Lahaina, HI
ONEIDA	ID	16071	44100	Ogden-Clearfield, UT
CHRISTIAN	IL	17021	14010	Springfield, IL
DE WITT	IL	17039	16580	Bloomington, IL
FORD	IL	17053	28100	Champaign-Urbana, IL
IROQUOIS	IL	17075	44100	Kankakee, IL
LOGAN	IL	17107	37900	Springfield, IL

Lugar County Name	State	FIPSCD	CBSA	CBSA Name
MASON	IL	17125	40420	Peoria, IL
OGLE	IL	17141	16060	Rockford, IL
UNION	IL	17181	29200	Carbondale-Marion, IL
CLINTON	IN	18023	14020	Lafayette-West Lafayette, IN
GREENE	IN	18055	26900	Bloomington, IN
HENRY	IN	18065	43780	Indianapolis-Carmel-Anderson, IN
MARSHALL	IN	18099	31140	South Bend-Mishawaka, IN-MI
SCOTT	IN	18143	21780	Louisville/Jefferson County, KY-IN
SPENCER	IN	18147	23844	Evansville, IN-KY
STARKE	IN	18149	26900	Gary, IN
TIPTON	IN	18159	23060	Indianapolis-Carmel-Anderson, IN
WELLS	IN	18179	47940	Fort Wayne, IN
BUCHANAN	IA	19019	26980	Waterloo-Cedar Falls, IA
CEDAR	IA	19031	20220	Iowa City, IA
DELAWARE	IA	19055	26980	Dubuque, IA
IOWA	IA	19095	43580	Iowa City, IA
PLYMOUTH	IA	19149	28140	Sioux City, IA-NE-SD
FRANKLIN	KS	20059	48620	Kansas City, MO-KS
KINGMAN	KS	20095	31140	Wichita, KS
NELSON	KY	21179	31140	Louisville/Jefferson County, KY-IN
TRIMBLE	KY	21223	29340	Louisville/Jefferson County, KY-IN
JEFFRSON DAVIS	LA	22053	29180	Lake Charles, LA
ST. LANDRY	LA	22097	43340	Lafayette, LA
WEBSTER	LA	22119	30340	Shreveport-Bossier City, LA
OXFORD	ME	23017	12580	Lewiston-Auburn, ME
CAROLINE	MD	24011	24340	Baltimore-Columbia-Towson, MD
ALLEGAN	MI	26005	24340	Grand Rapids-Kentwood, MI
BARRY	MI	26015	11460	Grand Rapids-Kentwood, MI
LENAWEE	MI	26091	24340	Ann Arbor, MI
NEWAYGO	MI	26123	40980	Grand Rapids-Kentwood, MI
TUSCOLA	MI	26157	28020	Saginaw, MI
VAN BUREN	MI	26159	33460	Kalamazoo-Portage, MI
GOODHUE	MN	27049	33460	Minneapolis-St. Paul-Bloomington, MN-WI
MEEKER	MN	27093	33460	Minneapolis-St. Paul-Bloomington, MN-WI
RICE	MN	27131	33460	Minneapolis-St. Paul-Bloomington, MN-WI
SIBLEY	MN	27143	32820	Minneapolis-St. Paul-Bloomington, MN-WI
BENTON	MS	28009	35380	Memphis, TN-MS-AR
PEARL RIVER	MS	28109	44180	New Orleans-Metairie, LA
DADE	MO	29057	22220	Springfield, MO
MC DONALD	MO	29119	13740	Fayetteville-Springdale-Rogers, AR

Lugar County Name	State	FIPSCD	CBSA	CBSA Name
GOLDEN VALLEY	MT	30037	24260	Billings, MT
HAMILTON	NE	31081	30700	Grand Island, NE
OTOE	NE	31131	16180	Lincoln, NE
DOUGLAS	NV	32005	16180	Carson City, NV
LYON	NV	32019	42140	Carson City, NV
MERRIMACK	NH	33013	31700	Manchester-Nashua, NH
LOS ALAMOS	NM	35028	45060	Santa Fe, NM
CAYUGA	NY	36011	10580	Manchester-Nashua, NH
COLUMBIA	NY	36021	27060	Syracuse, NY
CORTLAND	NY	36023	40380	Albany-Schenectady-Troy, NY
GENESEE	NY	36037	10580	Ithaca, NY
GREENE	NY	36039	48060	Rochester, NY
LEWIS	NY	36049	10580	Albany-Schenectady-Troy, NY
MONTGOMERY	NY	36057	27060	Watertown-Fort Drum, NY
SCHUYLER	NY	36097	40380	Albany-Schenectady-Troy, NY
SENECA	NY	36099	39100	Ithaca, NY
SULLIVAN	NY	36105	15500	Rochester, NY
CASWELL	NC	37033	24780	Poughkeepsie-Newburgh-Middletown, NY
GREENE	NC	37079	43900	Burlington, NC
POLK	NC	37149	40580	Greenville, NC
WILSON	NC	37195	24220	Spartanburg, SC
SIOUX	ND	38085	17460	Rocky Mount, NC
TRAILL	ND	38097	18140	Grand Forks, ND-MN
ASHTABULA	OH	39007	49660	Cleveland-Elyria, OH
CHAMPAIGN	OH	39021	48260	Columbus, OH
COLUMBIANA	OH	39029	19430	Youngstown-Warren-Boardman, OH-PA
HARRISON	OH	39067	22900	Weirton-Steubenville, WV-OH
PREBLE	OH	39135	48700	Dayton-Kettering, OH
LE FLORE	OK	40079	25180	Fort Smith, AR-OK
CLINTON	PA	42035	38300	Williamsport, PA
FULTON	PA	42057	38300	Hagerstown-Martinsburg, MD-WV
GREENE	PA	42059	39740	Pittsburgh, PA
LAWRENCE	PA	42073	42540	Pittsburgh, PA
SCHUYLKILL	PA	42107	16700	Reading, PA
SUSQUEHANNA	PA	42115	17900	Scranton--Wilkes-Barre, PA
COLLETON	SC	45029	22500	Charleston-North Charleston, SC
LEE	SC	45061	17900	Columbia, SC
MARION	SC	45067	43900	Florence, SC
NEWBERRY	SC	45071	39660	Columbia, SC
UNION	SC	45087	34980	Spartanburg, SC

Lugar County Name	State	FIPSCD	CBSA	CBSA Name
CUSTER	SD	46033	17420	Rapid City, SD
HICKMAN	TN	47081	18580	Nashville-Davidson--Murfreesboro--Franklin, TN
MEIGS	TN	47121	12420	Cleveland, TN
ARANSAS	TX	48007	47380	Corpus Christi, TX
BLANCO	TX	48031	19124	Austin-Round Rock-Georgetown, TX
BOSQUE	TX	48035	26420	Waco, TX
FANNIN	TX	48147	19124	Dallas-Plano-Irving, TX
GRIMES	TX	48185	23104	Houston-The Woodlands-Sugar Land, TX
HENDERSON	TX	48213	23104	Dallas-Plano-Irving, TX
HILL	TX	48217	12420	Fort Worth-Arlington-Grapevine, TX
HOOD	TX	48221	13140	Fort Worth-Arlington-Grapevine, TX
MILAM	TX	48331	23104	Austin-Round Rock-Georgetown, TX
NEWTON	TX	48351	19124	Beaumont-Port Arthur, TX
SOMERVELL	TX	48425	15180	Fort Worth-Arlington-Grapevine, TX
VAN ZANDT	TX	48467	16820	Dallas-Plano-Irving, TX
WILLACY	TX	48489	47894	Brownsville-Harlingen, TX
BUCKINGHAM	VA	51029	13980	Charlottesville, VA
CAROLINE	VA	51033	40060	Washington-Arlington-Alexandria, DC-VA-MD-WV
FLOYD	VA	51063	47894	Blacksburg-Christiansburg, VA
LOUISA	VA	51109	25500	Richmond, VA
ORANGE	VA	51137	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV
PAGE	VA	51139	47260	Harrisonburg, VA
SHENANDOAH	VA	51171	47460	Washington-Arlington-Alexandria, DC-VA-MD-WV
SURRY	VA	51181	42644	Virginia Beach-Norfolk-Newport News, VA-NC
COLUMBIA	WA	53013	36500	Walla Walla, WA
ISLAND	WA	53029	44060	Seattle-Bellevue-Kent, WA
MASON	WA	53045	16620	Olympia-Lacey-Tumwater, WA
PEND OREILLE	WA	53051	22540	Spokane-Spokane Valley, WA
ROANE	WV	54087	33340	Charleston, WV
GREEN LAKE	WI	55047	33340	Fond du Lac, WI
JEFFERSON	WI	55055	41980	Milwaukee-Waukesha, WI
WALWORTH	WI	55127	32420	Milwaukee-Waukesha, WI
COAMO	PR	72043	25020	San Juan-Bayamón-Caguas, PR
MARICAO	PR	72093	25020	Mayagüez, PR
SALINAS	PR	72123	25020	Guayama, PR

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J. Proposed Out-Migration Adjustment Based on Commuting Patterns of Hospital Employees

In accordance with section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, beginning with FY 2005, we established a process to make adjustments to the hospital wage index based on commuting patterns of hospital employees (the ''out-migration'' adjustment). The process, outlined in the FY 2005 IPPS final rule (69 FR 49061), provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index.

Section 1886(d)(13)(B) of the Act requires the Secretary to use data the Secretary determines to be appropriate to establish the qualifying counties. When the provision of section

1886(d)(13) of the Act was implemented for the FY 2005 wage index, we analyzed commuting data compiled by the U.S. Census Bureau that were derived from a special tabulation of the 2000 Census journey-to-work data for all industries (CMS extracted data applicable to hospitals). These data were compiled from responses to the ''long-form'' survey, which the Census Bureau used at that time and which contained questions on where residents in each county worked (69 FR 49062). However, the 2010 Census was ''short form'' only; information on where residents in each county worked was not collected as part of the 2010 Census. The Census Bureau worked with CMS to provide an alternative dataset based on the latest available data on where residents in each county worked in 2010, for use in developing a new outmigration adjustment based on new commuting patterns developed from the 2010 Census data beginning with FY 2016.

To determine the out-migration adjustments and applicable counties for FY 2016, we analyzed commuting data compiled by the Census Bureau that were derived from a custom tabulation of the American Community Survey (ACS), an official Census Bureau survey, utilizing 2008 through 2012 (5-year) Microdata. The data were compiled from responses to the ACS questions regarding the county where workers reside and the county to which workers commute. As we discussed in the FYs 2016 through 2020 IPPS/LTCH PPS final rules (80 FR 49501, 81 FR 56930, 82 FR 38150, 83 FR 41384, and 84 FR 42318 respectively), the same policies, procedures, and computation that were used for the FY 2012 out-migration adjustment were applicable for FYs 2016 through 2020, and we are proposing to use them again for FY 2021. We have applied the same policies, procedures, and computations since FY 2012, and we believe they continue to be appropriate for FY 2021. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49500 through 49502) for a full explanation of the revised data source.

For FY 2021, the out-migration adjustment will continue to be based on the data derived from the custom tabulation of the ACS utilizing 2008 through 2012 (5-year) Microdata. For future fiscal years, we may consider determining out-migration adjustments based on data from the next Census or other available data, as appropriate. For FY 2021, we are not proposing any changes to the methodology or data source that we used for FY 2016 (81 FR 25071). (We refer readers to a full discussion of the out-migration adjustment, including rules on deeming hospitals reclassified under section 1886(d)(8) or section 1886(d)(10) of the Act to have waived the out-migration adjustment, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51601 through 51602).)

Table 2 associated with this proposed rule (which is available via the internet on the CMS website) includes the proposed out-migration adjustments for the FY 2021 wage index. In addition, as discussed in the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20367), we have added a Table 4, ''List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act.'' For this proposed rule, Table 4 consists of the following: A list of counties that would be eligible for the out-migration adjustment for FY 2021 identified by FIPS county code, the proposed FY 2021 out-migration adjustment, and the number of years the adjustment would be in effect. We believe this table makes this information more transparent and provides the public with easier access to this information. We note that we intend to make the information available annually via Table 4 associated with the IPPS/LTCH PPS proposed and final rules, and are including it among the tables associated with this FY 2021 IPPS/LTCH PPS proposed rule that are available via the internet on the CMS website.

K. Reclassification From Urban to Rural Under Section 1886(d)(8)(E) of the Act Implemented at 42 CFR 412.103

1. Application for Rural Status and Lock-In Date

Under section 1886(d)(8)(E) of the Act, a qualifying prospective payment hospital located in an urban area may apply for rural status for payment purposes separate from reclassification through the MGCRB. Specifically, section 1886(d)(8)(E) of the Act provides that, not later than 60 days after the receipt of an application (in a form and manner determined by the Secretary) from a subsection (d) hospital that satisfies certain criteria, the Secretary shall treat the hospital as being located in the rural area (as defined in paragraph (2)(D)) of the State in which the hospital is located. We refer readers to the regulations at 42 CFR 412.103 for the general criteria and application requirements for a subsection (d) hospital to reclassify from urban to rural status in accordance with section 1886(d)(8)(E) of the Act. The FY 2012 IPPS/LTCH PPS final rule (76 FR 51595 through 51596) includes our policies regarding the effect of wage data from reclassified or redesignated hospitals. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336) for a discussion on our current policy to calculate the rural floor without the wage data of urban hospitals reclassifying to rural areas under 42 CFR 412.103.

Because the wage index is part of the methodology for determining the prospective payments to hospitals for each fiscal year, we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56931) that we believed there should be a definitive timeframe within which a hospital should apply for rural status in order for the reclassification to be reflected in the next Federal fiscal year's wage data used for setting payment rates. Therefore, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56931 through 56932), we revised § 412.103(b) by adding paragraph (6) to add a lock-in date by which a hospital's application for rural status must be filed in order to be treated as rural in the wage index and budget neutrality calculations for payment rates for the next Federal fiscal year. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41384 through 41386), we changed the lock-in date to provide for additional time in the ratesetting process and to match the lock-in date with another existing deadline, the usual public comment deadline for the IPPS proposed rule. We revised § 412.103(b)(6) to specify that, in order for a hospital to be treated as rural in the wage index and budget neutrality calculations under § 412.64(e)(1)(ii), (e)(2) and (4), and (h) for payment rates for the next Federal fiscal year, the hospital's application must be approved by the CMS Regional Office in accordance with the requirements of § 412.103 no later than 60 days after the public display date at the Office of the Federal Register of the IPPS proposed rule for the next Federal fiscal year.

The lock-in date does not affect the timing of payment changes occurring at the hospital-specific level as a result of reclassification from urban to rural under § 412.103. As we discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56931) and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41385 through 41386), this lock-in date also does not change the current regulation that allows hospitals that qualify under § 412.103(a) to request, at any time during a cost reporting period, to reclassify from urban to rural. A hospital's rural status and claims payment reflecting its rural status continue to be effective on the filing date of its reclassification application, which is the date the CMS Regional

Office receives the application, in accordance with § 412.103(d). The hospital's IPPS claims will be paid reflecting its rural status beginning on the filing date (the effective date) of the reclassification, regardless of when the hospital applies.

2. Proposed Change to the Regulations To Allow Electronic Submission of Appeals to the Administrator and Copy to CMS

The regulation at § 412.278(b)(1) addresses a hospital's request for the Administrator's review of an MGCRB decision. This regulation currently states that a request for Administrator review filed by facsimile (FAX) or other electronic means will not be accepted. In addition, § 412.278(b)(1) requires a hospital to mail a copy of its request for review to CMS's Hospital and Ambulatory Policy Group.

We believe that these policies of prohibiting electronic submission of requests for Administrator review and requiring paper copies to be mailed to CMS are outdated and overly restrictive. In the interest of burden reduction and to promote ease of requests, we are proposing to eliminate the prohibition on submitting a request by facsimile or other electronic means so that hospitals may also submit requests for Administrator review of MGCRB decisions electronically. In addition, we are proposing to require the hospital to submit an electronic copy of its request for review to CMS's Hospital and Ambulatory Policy Group. We are specifying that copies to CMS' Hospital and Ambulatory Policy Group should be submitted via email to *wageindex@cms.hhs.gov*.

Accordingly, we are proposing to revise the regulation at § 412.278(b)(1) to read: The hospital's request for review must be in writing and sent to the Administrator, in care of the Office of the Attorney Advisor. The request must be received by the Administrator within 15 days after the date the MGCRB issues its decision. The hospital must also submit an electronic copy of its request for review to CMS's Hospital and Ambulatory Policy Group.

3. Clarification of Applicable Rural Referral Center (RRC) Criteria for Purposes of Meeting Urban to Rural Reclassification at § 412.103(a)(3)

As discussed in section IV.D. of the preamble of this proposed rule, for purposes of qualifying for RRC classification, a rural hospital that does not meet the bed size requirement at § 412.96(b)(1)(ii) can qualify as an RRC if the hospital meets two mandatory prerequisites (a minimum case-mix index (CMI) and a minimum number of discharges), and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume). Specifically, a hospital may demonstrate that its case-mix index is at least equal to the national case-mix index value as established by CMS or the median case-mix index value for urban hospitals located in each region, in accordance with § 412.96(c)(1), and that it has a number of discharges at least equal to 5,000 discharges or, if less, the median number of discharges for urban hospitals located in each region, in accordance with § 412.96(c)(2). CMS publishes the national and regional case-mix index values and the national and regional number of discharges for the purpose of these criteria in the annual notice of prospective payment rates published in the **Federal Register**.

For purposes of qualifying for urban to rural reclassification under § 412.103, a hospital can demonstrate that it would qualify as a rural referral center as set forth in § 412.96, if the hospital were located in a rural area. This condition is set forth at § 412.103(a)(3).

It has come to our attention that there is some confusion regarding which fiscal year's published case mix index (CMI) or numbers of discharges criteria would be used in the situation where a hospital is seeking to meet the urban to rural reclassification criterion at § 412.103(a)(3) by meeting the alternative criteria at § 412.96(c): (1) The criteria published in the final rule in effect on the filing date of the hospital's § 412.103 application, or (2) the criteria that would be in effect during the fiscal year that any RRC classification would become effective (that is, the beginning of the hospital's cost reporting period).

Therefore, we are clarifying that for purposes of meeting the urban to rural reclassification criterion at § 412.103(a)(3), the appropriate CMI values and numbers of discharges to demonstrate RRC eligibility are those published in the IPPS/LTCH PPS final rule in effect as of the filing date (that is, the effective date) of the hospital's application for reclassification under § 412.103. For purposes of RRC classification under § 412.96(c), the appropriate CMI values and numbers of discharges are those published in the IPPS/LTCH PPS final rule in effect when the RRC classification will be effective at the start of the hospital's next cost reporting period, consistent with § 412.96(h)(3) and (i)(3).

For example, Hospital A has a cost reporting period beginning October 1. It applies on September 1, 2020 for urban to rural reclassification under § 412.103(a)(3) and for RRC status, by meeting the alternative criteria at § 412.96(c). For Hospital A's urban to rural reclassification request, the appropriate national or regional CMI value and number of discharges that the hospital must meet or exceed are the values published in the FY 2020 IPPS/LTCH PPS Final Rule since that is the rule in effect as of the filing date (that is, effective date) of Hospital A's urban to rural reclassification application. For the RRC classification request, the appropriate national or regional CMI value and number of discharges that the hospital must meet or exceed are the values published in the FY 2021 IPPS/LTCH PPS final rule since that is the rule that will be in effect when the RRC classification will become effective at the start of the hospital's next cost reporting period. We note that this policy applies regardless of whether a hospital seeks only § 412.103 rural reclassification, or § 412.103 rural reclassification along with RRC classification.

We believe our policy is appropriate considering that a hospital may apply for rural reclassification under § 412.103 at any time, as previously discussed in section III.K.1. of the preamble of this proposed rule. We clarified in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38151) that while applications for RRC status must be submitted during the last quarter of a hospital's cost reporting period in accordance with section 1886(d)(5)(C)(i) of the Act, applications for rural reclassification may be submitted at any time, including applications of hospitals seeking rural reclassification under § 412.103(a)(3). A hospital is permitted at any time to submit an urban to rural reclassification request on the basis of qualifying for RRC status under § 412.103(a)(3), even before the publication of the CMI and discharge criteria in the IPPS/LTCH PPS final rule for the period in which any RRC classification would be effective (that is, the start of the hospital's next cost reporting period).

L. Process for Requests for Wage Index Data Corrections

1. Process for Hospitals To Request Wage Index Data Corrections

The preliminary, unaudited Worksheet S–3 wage data files and the preliminary CY 2016 occupational mix data files for the proposed FY 2021 wage index were made available on May 17, 2019 through the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-*

Index-Files-Items/FY2021-Wage-Index-Home-Page.

On January 31, 2020, we posted a public use file (PUF) at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2021-Wage-Index-Home-Page* containing FY 2021 wage index data available as of January 30, 2020. This PUF contains a tab with the Worksheet S–3 wage data (which includes Worksheet S–3, Parts II and III wage data from cost reporting periods beginning on or after October 1, 2016 through September 30, 2017; that is, FY 2017 wage data), a tab with the occupational mix data (which includes data from the CY 2016 occupational mix survey, Form CMS–10079), a tab containing the Worksheet S–3 wage data of hospitals deleted from the January 31, 2020 wage data PUF, and a tab containing the CY 2016 occupational mix data of the hospitals deleted from the January 31, 2020 occupational mix PUF. In a memorandum dated January 29, 2020, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the January 31, 2020 wage index data PUFs, and the process and timeframe for requesting revisions in accordance with the FY 2021 Wage Index Timetable.

In the interest of meeting the data needs of the public, beginning with the proposed FY 2009 wage index, we post an additional PUF on the CMS website that reflects the actual data that are used in computing the proposed wage index. The release of this file does not alter the current wage index process or schedule. We notify the hospital community of the availability of these data as we do with the current public use wage data files through our Hospital Open Door Forum. We encourage hospitals to sign up for automatic notifications of information about hospital issues and about the dates of the Hospital Open Door Forums at the CMS website at: *http://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/index.html*.

In a memorandum dated April 29, 2019, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the preliminary wage index data files and the CY 2016 occupational mix survey data files posted on May 17, 2019, and the process and timeframe for requesting revisions.

If a hospital wished to request a change to its data as shown in the May 17, 2019 preliminary wage and occupational mix data files, the hospital had to submit corrections along with complete, detailed supporting documentation to its MAC so that the MAC received them by September 3, 2019. Hospitals were notified of this deadline and of all other deadlines and requirements, including the requirement to review and verify their data as posted in the preliminary wage index data files on the internet, through the letters sent to them by their MACs. November 15, 2019 was the deadline for MACs to complete all desk reviews for hospital wage and occupational mix data and transmit revised Worksheet S–3 wage data and occupational mix data to CMS.

November 5, 2019 was the date by when MACs notified State hospital associations regarding hospitals that failed to respond to issues raised during the desk reviews. Additional revisions made by the MACs were transmitted to CMS throughout January 2020. CMS published the wage index PUFs that included hospitals' revised wage index data on January 31, 2020. Hospitals had until February 14, 2020, to submit requests to the MACs to correct errors in the January 31, 2020 PUF due to CMS or MAC mishandling of the wage index data, or to revise desk review adjustments to their wage index data as included in the January 31, 2020 PUF. Hospitals also were required to submit sufficient documentation to support their requests. Hospitals' requests and supporting documentation must be received by the MAC by the February deadline (that is, by February 14, 2020 for the FY 2021 wage index).

After reviewing requested changes submitted by hospitals, MACs were required to transmit to CMS any additional revisions resulting from the hospitals' reconsideration requests by March 19, 2020. Under our current policy as adopted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38153), the deadline for a hospital to request CMS intervention in cases where a hospital disagreed with a MAC's handling of wage data on any basis (including a policy, factual, or other dispute) was April 2, 2020. Data that were incorrect in the preliminary or January 31, 2020 wage index data PUFs, but for which no correction request was received by the February 14, 2020 deadline, are not considered for correction at this stage. In addition, April 2, 2020 was the deadline for hospitals to dispute data corrections made by CMS of which the hospital is notified after the January 31, 2020 PUF and at least 14 calendar days prior to April 2, 2020 (that is, March 19, 2020), that do not arise from a hospital's request for revisions. The hospital's request and supporting documentation must be received by CMS (and a copy received by the MAC) by the April deadline (that is, by April 2, 2020 for the FY 2021 wage index). We refer readers to the wage index timeline for complete details.

Hospitals are given the opportunity to examine Table 2 associated with this proposed rule, which is listed in section VI. of the Addendum to this proposed rule and available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2021-IPPS-Proposed-Rule-Home-Page.html*. Table 2 contains each hospital's proposed adjusted average hourly wage used to construct the wage index values for the past 3 years, including the FY 2017 data used to construct the proposed FY 2021 wage index. We note that the proposed hospital average hourly wages shown in Table 2 only reflect changes made to a hospital's data that were transmitted to CMS by early February 2020.

We plan to post the final wage index data PUFs in late April 2020 via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2021-Wage-Index-Home-Page*. The April 2020 PUFs are made available solely for the limited purpose of identifying any potential errors made by CMS or the MAC in the entry of the final wage index data that resulted from the correction process previously described (the process for disputing revisions submitted to CMS by the MACs by March 19, 2020, and the process for disputing data corrections made by CMS that did not arise from a hospital's request for wage data revisions as discussed earlier).

After the release of the April 2020 wage index data PUFs, changes to the wage and occupational mix data can only be made in those very limited situations involving an error by the MAC or CMS that the hospital could not have known about before its review of the final wage index data files. Specifically, neither the MAC nor CMS will approve the following types of requests:

- Requests for wage index data corrections that were submitted too late to be included in the data transmitted to CMS by the MACs on or before March 19, 2020.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the January 31, 2020 wage index PUFs.
- Requests to revisit factual determinations or policy interpretations made by the MAC or CMS during the wage index data correction process.

If, after reviewing the April 2020 final wage index data PUFs, a hospital

believes that its wage or occupational mix data are incorrect due to a MAC or CMS error in the entry or tabulation of the final data, the hospital is given the opportunity to notify both its MAC and CMS regarding why the hospital believes an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). The hospital is required to send its request to CMS and to the MAC so that it is received no later than May 29, 2020. May 29, 2020 is also the deadline for hospitals to dispute data corrections made by CMS of which the hospital is notified on or after 13 calendar days prior to April 2, 2019 (that is, March 20, 2020), and at least 14 calendar days prior to May 29, 2020 (that is, May 15, 2020), that do not arise from a hospital's request for revisions. (Data corrections made by CMS of which a hospital is notified on or after 13 calendar days prior to May 29, 2020 (that is, May 16, 2020) may be appealed to the Provider Reimbursement Review Board (PRRB)). In accordance with the FY 2021 wage index timeline posted on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY-2021-Hospital-Wage-Index-Development-Time-Table.pdf*, the May appeals must be sent via mail and email to CMS and the MACs. We refer readers to the wage index timeline for complete details.

Verified corrections to the wage index data received timely (that is, by May 29, 2020) by CMS and the MACs will be incorporated into the final FY 2021 wage index, which will be effective October 1, 2020.

We created the processes previously described to resolve all substantive wage index data correction disputes before we finalize the wage and occupational mix data for the FY 2021 payment rates. Accordingly, hospitals that do not meet the procedural deadlines set forth earlier will not be afforded a later opportunity to submit wage index data corrections or to dispute the MAC's decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines as previously set forth (requiring requests to MACs by the specified date in February and, where such requests are unsuccessful, requests for intervention by CMS by the specified date in April) will not be permitted to challenge later, before the PRRB, the failure of CMS to make a requested data revision. We refer readers also to the FY 2000 IPPS final rule (64 FR 41513) for a discussion of the parameters for appeals to the PRRB for wage index data corrections. As finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156), this policy also applies to a hospital disputing corrections made by CMS that do not arise from a hospital's request for a wage index data revision. That is, a hospital disputing an adjustment made by CMS that did not arise from a hospital's request for a wage index data revision would be required to request a correction by the first applicable deadline. Hospitals that do not meet the procedural deadlines set forth earlier will not be afforded a later opportunity to submit wage index data corrections or to dispute CMS' decision with respect to changes.

Again, we believe the wage index data correction process described earlier provides hospitals with sufficient opportunity to bring errors in their wage and occupational mix data to the MAC's attention. Moreover, because hospitals have access to the final wage index data PUFs by late April 2020, they have the opportunity to detect any data entry or tabulation errors made by the MAC or CMS before the development and publication of the final FY 2021 wage index by August 2020, and the implementation of the FY 2021 wage index on October 1, 2020. Given these processes, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are identified by hospitals and brought to our attention after May 29, 2020, we retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with 42 CFR 412.64(k)(1) of our regulations, we make midyear corrections to the wage index for an area only if a hospital can show that: (1) The MAC or CMS made an error in tabulating its data; and (2) the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of the fiscal year. For purposes of this provision, ''before the beginning of the fiscal year'' means by the May deadline for making corrections to the wage data for the following fiscal year's wage index (for example, May 29, 2020 for the FY 2021 wage index). This provision is not available to a hospital seeking to revise another hospital's data that may be affecting the requesting hospital's wage index for the labor market area. As indicated earlier, because CMS makes the wage index data available to hospitals on the CMS website prior to publishing both the proposed and final IPPS rules, and the MACs notify hospitals directly of any wage index data changes after completing their desk reviews, we do not expect that midyear corrections will be necessary. However, under our current policy, if the correction of a data error changes the wage index value for an area, the revised wage index value will be effective prospectively from the date the correction is made.

In the FY 2006 IPPS final rule (70 FR 47385 through 47387 and 47485), we revised 42 CFR 412.64(k)(2) to specify that, effective on October 1, 2005, that is, beginning with the FY 2006 wage index, a change to the wage index can be made retroactive to the beginning of the Federal fiscal year only when CMS determines all of the following: (1) The MAC or CMS made an error in tabulating data used for the wage index calculation; (2) the hospital knew about the error and requested that the MAC and CMS correct the error using the established process and within the established schedule for requesting corrections to the wage index data, before the beginning of the fiscal year for the applicable IPPS update (that is, by the May 29, 2020 deadline for the FY 2021 wage index); and (3) CMS agreed before October 1 that the MAC or CMS made an error in tabulating the hospital's wage index data and the wage index should be corrected.

In those circumstances where a hospital requested a correction to its wage index data before CMS calculated the final wage index (that is, by the May 29, 2020 deadline for the FY 2021 wage index), and CMS acknowledges that the error in the hospital's wage index data was caused by CMS' or the MAC's mishandling of the data, we believe that the hospital should not be penalized by our delay in publishing or implementing the correction. As with our current policy, we indicated that the provision is not available to a hospital seeking to revise another hospital's data. In addition, the provision cannot be used to correct prior years' wage index data; and it can only be used for the current Federal fiscal year. In situations where our policies would allow midyear corrections other than those specified in 42 CFR 412.64(k)(2)(ii), we continue to believe that it is appropriate to make prospective-only corrections to the wage index.

We note that, as with prospective changes to the wage index, the final retroactive correction will be made irrespective of whether the change increases or decreases a hospital's payment rate. In addition, we note that the policy of retroactive adjustment will still apply in those instances where a final judicial decision reverses a CMS denial of a hospital's wage index data revision request.

2. Process for Data Corrections by CMS After the January 31 Public Use File (PUF)

The process set forth with the wage index timeline discussed in section III.L.1. of the preamble of this proposed rule allows hospitals to request corrections to their wage index data within prescribed timeframes. In addition to hospitals' opportunity to request corrections of wage index data errors or MACs' mishandling of data, CMS has the authority under section 1886(d)(3)(E) of the Act to make corrections to hospital wage index and occupational mix data in order to ensure the accuracy of the wage index. As we explained in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49490 through 49491) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56914), section 1886(d)(3)(E) of the Act requires the Secretary to adjust the proportion of hospitals' costs attributable to wages and wage-related costs for area differences reflecting the relative hospital wage level in the geographic areas of the hospital compared to the national average hospital wage level. We believe that, under section 1886(d)(3)(E) of the Act, we have discretion to make corrections to hospitals' data to help ensure that the costs attributable to wages and wage-related costs in fact accurately reflect the relative hospital wage level in the hospitals' geographic areas.

We have an established multistep, 15-month process for the review and correction of the hospital wage data that is used to create the IPPS wage index for the upcoming fiscal year. Since the origin of the IPPS, the wage index has been subject to its own annual review process, first by the MACs, and then by CMS. As a standard practice, after each annual desk review, CMS reviews the results of the MACs' desk reviews and focuses on items flagged during the desk review, requiring that, if necessary, hospitals provide additional documentation, adjustments, or corrections to the data. This ongoing communication with hospitals about their wage data may result in the discovery by CMS of additional items that were reported incorrectly or other data errors, even after the posting of the January 31 PUF, and throughout the remainder of the wage index development process. In addition, the fact that CMS analyzes the data from a regional and even national level, unlike the review performed by the MACs that review a limited subset of hospitals, can facilitate additional editing of the data that may not be readily apparent to the MACs. In these occasional instances, an error may be of sufficient magnitude that the wage index of an entire CBSA is affected. Accordingly, CMS uses its authority to ensure that the wage index accurately reflects the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level, by continuing to make corrections to hospital wage data upon discovering incorrect wage data, distinct from instances in which hospitals request data revisions.

We note that CMS corrects errors to hospital wage data as appropriate, regardless of whether that correction will raise or lower a hospital's average hourly wage. For example, as discussed in section III.C. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41364), in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). Furthermore, if CMS discovers after conclusion of the desk review, for example, that a MAC inadvertently failed to incorporate positive adjustments resulting from a prior year's wage index appeal of a hospital's wage-related costs such as pension, CMS would correct that data error and the hospital's average hourly wage would likely increase as a result.

While we maintain CMS' authority to conduct additional review and make resulting corrections at any time during the wage index development process, in accordance with the policy finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156) and as first implemented with the FY 2019 wage index (83 FR 41389), hospitals are able to request further review of a correction made by CMS that did not arise from a hospital's request for a wage index data correction. Instances where CMS makes a correction to a hospital's data after the January 31 PUF based on a different understanding than the hospital about certain reported costs, for example, could potentially be resolved using this process before the final wage index is calculated. We believe this process and the timeline for requesting such corrections (as described earlier and in the FY 2018 IPPS/LTCH PPS final rule) promote additional transparency to instances where CMS makes data corrections after the January 31 PUF, and provide opportunities for hospitals to request further review of CMS changes in time for the most accurate data to be reflected in the final wage index calculations. These additional appeals opportunities are described earlier and in the FY 2021 Wage Index Development Time Table, as well as in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156).

3. Update to Wage Index Development Timetable To Include Time Zone for Deadlines

During the FY 2021 Wage Index development process, we received inquiries regarding the time zone for deadlines in the Wage Index Development Timetable. Specifically, hospitals asked if revision requests submitted after 11:59 p.m. Eastern Standard Time (EST) could be accepted if the deadline had not yet passed in the time zone where the hospitals are located. The current timetable does not specify time zones. To eliminate confusion and promote clear deadlines, we are proposing to use Eastern Standard Time (EST) as the time zone for wage index deadlines after October 1, 2020 on the FY 2022 Wage Index Development Timetable. We believe using one time zone is important for a clear and consistent deadline for all hospitals. We also believe that EST is an appropriate time zone for the deadline because CMS's central office headquarters are located in the EST and because it is consistent with the time zone used for other CMS deadlines, such as the deadline to register to report certain quality data via the CMS Web Interface (see the Registration Guide available for download at *https://qpp.cms.gov/mips/how-to-register-for-CMS-WI-and-CAHPS*) and applications for ACOs to participate in the Shared Savings Program (see deadlines outlined at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/for-acos/application-types-and-timeline*, in accordance with § 425.202). We welcome commenters' input on which time zone is most reasonable for all hospitals and appropriate for supporting consistent, clear deadlines.

M. Proposed Labor-Related Share for the Proposed FY 2021 Wage Index

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related and to adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs that are attributable to wages and wage-related costs of the

DRG prospective payment rates. We refer to the portion of hospital costs attributable to wages and wage-related costs as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index.

Section 403 of Public Law 108–173 amended section 1886(d)(3)(E) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this would result in lower payments to a hospital than would otherwise be made. However, this provision of Public Law 108–173 did not change the legal requirement that the Secretary estimate from time to time the proportion of hospitals' costs that are attributable to wages and wage-related costs. Thus, hospitals receive payment based on either a 62-percent labor-related share, or the labor-related share estimated from time to time by the Secretary, depending on which labor-related share resulted in a higher payment.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38158 through 38175), we rebased and revised the hospital market basket. We established a 2014-based IPPS hospital market basket to replace the FY 2010-based IPPS hospital market basket, effective October 1, 2017. Using the 2014-based IPPS market basket, we finalized a labor-related share of 68.3 percent for discharges occurring on or after October 1, 2017. In addition, in FY 2018, we implemented this revised and rebased labor-related share in a budget neutral manner (82 FR 38522). However, consistent with section 1886(d)(3)(E) of the Act, we did not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0000 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0000. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42325), for FY 2020, we continued to use a labor-related share of 68.3 percent for discharges occurring on or after October 1, 2019.

The labor-related share is used to determine the proportion of the national IPPS base payment rate to which the area wage index is applied. We include a cost category in the labor-related share if the costs are labor intensive and vary with the local labor market. In this proposed rule, for FY 2021, we are not proposing to make any further changes to the national average proportion of operating costs that are attributable to wages and salaries, employee benefits, professional fees: Labor-related, administrative and facilities support services, installation, maintenance, and repair services, and all other labor-related services. Therefore, for FY 2021, we are proposing to continue to use a labor-related share of 68.3 percent for discharges occurring on or after October 1, 2020.

As discussed in section IV.B. of the preamble of this proposed rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we applied the Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage to the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need for us to calculate a Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage for application to the Puerto Rico-specific standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national labor-related share and nonlabor-related share percentages that are applied to the national standardized amount. Accordingly, for FY 2021, we are not proposing a Puerto Rico-specific labor-related share percentage or a nonlabor-related share percentage.

Tables 1A and 1B, which are published in section VI. of the Addendum to this FY 2021 IPPS/LTCH PPS proposed rule and available via the internet on the CMS website, reflect the proposed national labor-related share, which is also applicable to Puerto Rico hospitals. For FY 2021, for all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are less than or equal to 1.0000, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.000, for FY 2021, we are proposing to apply the wage index to a proposed labor-related share of 68.3 percent of the national standardized amount.

IV. Other Decisions and Changes to the IPPS for Operating System

A. Proposed Changes to MS–DRGs Subject to Postacute Care Transfer Policy and MS–DRG Special Payments Policies (§ 412.4)

1. Background

Existing regulations at 42 CFR 412.4(a) define discharges under the IPPS as situations in which a patient is formally released from an acute care hospital or dies in the hospital. Section 412.4(b) defines acute care transfers, and § 412.4(c) defines postacute care transfers. Our policy set forth in § 412.4(f) provides that when a patient is transferred and his or her length of stay is less than the geometric mean length of stay for the MS–DRG to which the case is assigned, the transferring hospital is generally paid based on a graduated per diem rate for each day of stay, not to exceed the full MS–DRG payment that would have been made if the patient had been discharged without being transferred.

The per diem rate paid to a transferring hospital is calculated by dividing the full MS–DRG payment by the geometric mean length of stay for the MS–DRG. Based on an analysis that showed that the first day of hospitalization is the most expensive (60 FR 45804), our policy generally provides for payment that is twice the per diem amount for the first day, with each subsequent day paid at the per diem amount up to the full MS–DRG payment (§ 412.4(f)(1)). Transfer cases also are eligible for outlier payments. In general, the outlier threshold for transfer cases, as described in § 412.80(b), is equal to the fixed-loss outlier threshold for nontransfer cases (adjusted for geographic variations in costs), divided by the geometric mean length of stay for the MS–DRG, and multiplied by the length of stay for the case, plus 1 day.

We established the criteria set forth in § 412.4(d) for determining which DRGs qualify for postacute care transfer payments in the FY 2006 IPPS final rule (70 FR 47419 through 47420). The determination of whether a DRG is subject to the postacute care transfer policy was initially based on the Medicare Version 23.0 GROUPER (FY 2006) and data from the FY 2004 MedPAR file. However, if a DRG did not exist in Version 23.0 or a DRG included in Version 23.0 is revised, we use the current version of the Medicare GROUPER and the most recent complete year of MedPAR data to determine if the DRG is subject to the postacute care

transfer policy. Specifically, if the MS–DRG's total number of discharges to postacute care equals or exceeds the 55th percentile for all MS–DRGs and the proportion of short-stay discharges to postacute care to total discharges in the MS–DRG exceeds the 55th percentile for all MS–DRGs, CMS will apply the postacute care transfer policy to that MS–DRG and to any other MS–DRG that shares the same base MS–DRG. The statute directs us to identify MS–DRGs based on a high volume of discharges to postacute care facilities and a disproportionate use of postacute care services. As discussed in the FY 2006 IPPS final rule (70 FR 47416), we determined that the 55th percentile is an appropriate level at which to establish these thresholds. In that same final rule (70 FR 47419), we stated that we will not revise the list of DRGs subject to the postacute care transfer policy annually unless we are making a change to a specific MS–DRG.

To account for MS–DRGs subject to the postacute care policy that exhibit exceptionally higher shares of costs very early in the hospital stay, § 412.4(f) also includes a special payment methodology. For these MS–DRGs, hospitals receive 50 percent of the full MS–DRG payment, plus the single per diem payment, for the first day of the stay, as well as a per diem payment for subsequent days (up to the full MS–DRG payment (§ 412.4(f)(6)). For an MS–DRG to qualify for the special payment methodology, the geometric mean length of stay must be greater than 4 days, and the average charges of 1-day discharge cases in the MS–DRG must be at least 50 percent of the average charges for all cases within the MS–DRG. MS–DRGs that are part of an MS–DRG severity level group will qualify under the MS–DRG special payment methodology policy if any one of the MS–DRGs that share that same base MS–DRG qualifies (§ 412.4(f)(6)).

Prior to the enactment of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), under section 1886(d)(5)(J) of the Act, a discharge was deemed a ''qualified discharge'' if the individual was discharged to one of the following postacute care settings:

- A hospital or hospital unit that is not a subsection (d) hospital.
- A skilled nursing facility.
- Related home health services provided by a home health agency provided within a timeframe established by the Secretary (beginning within 3 days after the date of discharge).

Section 53109 of the Bipartisan Budget Act of 2018 amended section 1886(d)(5)(J)(ii) of the Act to also include discharges to hospice care provided by a hospice program as a qualified discharge, effective for discharges occurring on or after October 1, 2018. Accordingly, effective for discharges occurring on or after October 1, 2018, if a discharge is assigned to one of the MS–DRGs subject to the postacute care transfer policy and the individual is transferred to hospice care by a hospice program, the discharge is subject to payment as a transfer case. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41394), we made conforming amendments to § 412.4(c) of the regulation to include discharges to hospice care occurring on or after October 1, 2018 as qualified discharges. We specified that hospital bills with a Patient Discharge Status code of 50 (Discharged/Transferred to Hospice—Routine or Continuous Home Care) or 51 (Discharged/Transferred to Hospice, General Inpatient Care or Inpatient Respite) are subject to the postacute care transfer policy in accordance with this statutory amendment. Consistent with our policy for other qualified discharges, CMS claims processing software has been revised to identify cases in which hospice benefits were billed on the date of hospital discharge without the appropriate discharge status code. Such claims will be returned as unpayable to the hospital and may be rebilled with a corrected discharge code.

2. Proposed Changes for FY 2021

As discussed in section II.F. of the preamble of the FY 2021 IPPS/LTCH PPS proposed rule, based on our analysis of FY 2019 MedPAR claims data, we are proposing to make changes to a number of MS–DRGs, effective for FY 2021. Specifically, we are proposing to do the following:

- Reassign procedure codes from MS–DRG 16 (Autologous Bone Marrow Transplant with CC/MCC or T-Cell Immunotherapy) to create new MS–DRG 18 (Chimeric Antigen Receptor [CAR] T-cell Immunotherapy) for cases reporting the administration of CAR T-cell therapy.
- Create new MS–DRG 019 (Simultaneous Pancreas and Kidney Transplant with Hemodialysis).
- Reassign procedures involving head, face, neck, ear, nose, mouth, or throat by creating six new MS–DRGs 140–142 (Major Head and Neck Procedures with MCC, with CC, and without CC/MCC, respectively) and 143–145 (Other Ear, Nose, Mouth and Throat O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) and deleting MS–DRGs 129–130 (Major Head and Neck Procedures with CC/MCC or Major Device, and without CC/MCC, respectively, MS–DRGs 131–132 (Cranial and Facial Procedures with CC/MCC and without CC/MCC, respectively) and MS–DRGs 133–134 (Other Ear, Nose, Mouth and Throat O.R. Procedures with CC/MCC and without CC/MCC, respectively).
- Reassign procedure codes from MS–DRGs 469–470 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement, and without MCC, respectively) and create two new MS–DRGs, 521 and 522 (Hip Replacement with Principal Diagnosis of Hip Fracture with MCC and without MCC, respectively) for cases reporting a hip replacement procedure with a principal diagnosis of a hip fracture.
- Reassign procedure codes from MS–DRG 652 (Kidney Transplant) into two new MS–DRGs, 650 and 651 (Kidney Transplant with Hemodialysis with MCC and without MCC, respectively) for cases reporting hemodialysis with a kidney transplant during the same admission.

In light of the proposed changes to these MS–DRGs for FY 2021, according to the regulations under § 412.4(d), we evaluated these MS–DRGs using the general postacute care transfer policy criteria and data from the FY 2019 MedPAR file. If an MS–DRG qualified for the postacute care transfer policy, we also evaluated that MS–DRG under the special payment methodology criteria according to regulations at § 412.4(f)(6). We continue to believe it is appropriate to assess newly proposed MS–DRGs and reassess revised MS–DRGs when proposing reassignment of procedure codes or diagnosis codes that would result in material changes to an MS–DRG. MS–DRGs 469 and 470 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement, and without MCC, respectively) are currently subject to the postacute care transfer policy, and as proposed to be revised, would continue to qualify to be included on the list of MS–DRGs that are subject to the postacute care transfer policy. Proposed new MS–DRGs 521 and 522 (Hip Replacement with Principal Diagnosis of Hip Fracture with MCC and without MCC, respectively) would also qualify to be included on the list of MS–DRGs that are subject to the postacute care transfer policy. We are therefore proposing to add MS–DRGs 521 and 522 to the list of MS–DRGs that are subject to the postacute care transfer policy. We note that MS–DRGs that are subject to the postacute transfer policy for FY 2020 and are not revised will continue to be subject to the policy in FY 2021.

Using the December 2019 update of the FY 2019 MedPAR file, we developed the following chart which sets forth the analysis of the postacute care transfer policy criteria completed for this proposed rule with respect to each of these proposed new or revised MS–DRGs. For the FY 2021 final rule, we intend to update this analysis using the most recent available data at that time.

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LIST OF PROPOSED NEW OR REVISED MS-DRGs SUBJECT TO REVIEW OF POSTACUTE CARE TRANSFER POLICY STATUS FOR FY 2021

Proposed New or Revised MS-DRGs	MS-DRG Title	Total Cases	Postacute Care Transfers (55th percentile: 1,378)	Short-Stay Postacute Care Transfers	Percent of Short-Stay Postacute Care Transfers to all Cases (55th percentile: 9.5089%)	Current Postacute Care Transfer Policy Status	Proposed Postacute Care Transfer Policy Status
016	Autologous Bone Marrow Transplant with CC/MCC	2,119	473*	141	6.6541*	No	No
018	Chimeric Antigen Receptor (CAR) T-cell Immunotherapy	303	82*	16	5.2805*	New	No
019	Simultaneous Pancreas and Kidney Transplant with Hemodialysis	86	32*	14	16.2791	New	No
140	Major Head and NeckProcedures with MCC	649	378*	96	14.7920	New	No
141	MajorHead and Neck Procedures with CC	2,485	796*	82	3.2998*	New	No
142	Major Head and Neck Procedures without CC/MCC	1,371	219*	20	1.4588*	New	No
143	Other Ear, Nose, Mouth and Throat O.R. Procedures with MCC	755	356*	37	9.6689	New	No
144	Other Ear, Nose, Mouth and Throat O.R. Procedures with CC	1,591	457*	67	4.2112*	New	No
145	Other Ear, Nose, Mouth and Throat O.R. Procedures without CC/MCC	1,083	142*	0	0*	New	No
469	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement	12,267	8,250	1484	12.0975	Yes	Yes
470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC	358,203	223,426	0	0*	Yes	Yes**
521	Hip Replacement with Principal Diagnosis of Hip Fracture with MCC	14,946	13,425	5834	39.0339	New	Yes
522	Hip Replacement with Principal Diagnosis of Hip Fracture without MCC	50,215	45,844	15,908	31.6798	New	Yes
650	Kidney Transplant with Hemodialysis with MCC	2,252	745*	200	7.837*	New	No
651	Kidney Transplant with Hemodialysis without MCC	1,144	349*	74	6.4685*	New	No
652	Kidney Transplant	9,081	1,856	346	4.7267*	No	No

* Indicates a current postacute care transfer policy criterion that the MS-DRG did not meet.

** As described in the policy at 42 CFR 412.4(d)(3)(ii)(D), MS-DRGs that share the same base MS-DRG will all qualify under the postacute care transfer policy if any one of the MS-DRGs that share that same base MS-DRG qualifies.

Based on our annual review of proposed new or revised MS–DRGs and analysis of the December 2019 update of the FY 2019 MedPAR file, we identified MS–DRGs that we are proposing to include on the list of MS–DRGs subject to the special payment policy methodology. Based on our analysis of proposed changes to MS–DRGs included in this proposed rule, we determined that proposed MS–DRGs 521 and 522 (Hip Replacement with Principal Diagnosis of Hip Fracture with MCC and without MCC, respectively) would meet the criteria for the MS–DRG special payment methodology. Therefore, we are proposing that proposed MS–DRGs 521 and 522 would be subject to the MS–DRG special payment methodology, effective FY 2021.

For the FY 2021 final rule, we intend to update this analysis using the most recent available data at that time.

LIST OF PROPOSED NEW OR REVISED MS-DRGs SUBJECT TO REVIEW OF SPECIAL PAYMENT POLICY STATUS FOR FY 2021

Proposed Revised MS-DRG	MS-DRG Title	Geometric Mean Length of Stay	Average Charges of 1-Day Discharges	50 Percent of Average Charges for all Cases within MS-DRG	Current Special Payment Policy Status	Proposed Special Payment Policy Status
469	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement	3.1193*	$83,575	$51,437	No	No
470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC	1.7758*	$59,972	$31,997	No	No
521	Hip Replacement with Principal Diagnosis of Hip Fracture with MCC	6.1668	$54,106	$51,941	New	Yes
522	Hip Replacement with Principal Diagnosis of Hip Fracture without MCC	4.0984	$66,589	$37,635	New	Yes

* Indicates a special payment policy criterion that the MS-DRG did not meet.

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The proposed postacute care transfer and special payment policy status of these MS–DRGs is reflected in Table 5 associated with this proposed rule, which is listed in section VI. of the Addendum to this proposed rule and available via the internet on the CMS website.

B. Proposed Changes in the Inpatient Hospital Update for FY 2021 (§ 412.64(d))

1. Proposed FY 2021 Inpatient Hospital Update

In accordance with section 1886(b)(3)(B)(i) of the Act, each year we update the national standardized amount for inpatient hospital operating costs by a factor called the ''applicable percentage increase.'' For FY 2021, we are setting the applicable percentage increase by applying the adjustments listed in this section in the same sequence as we did for FY 2020. (We note that section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.) Specifically, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. The applicable percentage increase under the IPPS for FY 2021 is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to all of the following:

- A reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act.
- A reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act.
- An adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment).

Section 1886(b)(3)(B)(xi) of the Act, as added by section 3401(a) of the Affordable Care Act, states that application of the MFP adjustment may result in the applicable percentage increase being less than zero.

In compliance with section 404 of the MMA, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38158 through 38175), we replaced the FY 2010-based IPPS operating market basket with the rebased and revised 2014-based IPPS operating market basket, effective with FY 2018.

We are proposing to base the proposed FY 2021 market basket update used to determine the applicable percentage increase for the IPPS on IHS Global Inc.'s (IGI's) fourth quarter 2019 forecast of the 2014-based IPPS market basket rate-of-increase with historical data through third quarter 2019, which is estimated to be 3.0 percent. We also are proposing that if more recent data subsequently become available (for example, a more recent estimate of the market basket and the MFP adjustment), we would use such data, if appropriate, to determine the FY 2021 market basket update and the MFP adjustment in the final rule.

For FY 2021, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the standardized amount, as specified in the table that appears later in this section.

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. As we explained in that rule, section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, defines this

productivity adjustment as 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 fiscal year, calendar year, cost reporting period, or other annual period). The 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.

MFP is derived by subtracting the contribution of labor and capital input growth from output growth. The projections of the components of MFP are currently produced by IGI, a nationally recognized economic forecasting firm with which CMS contracts to forecast the components of the market baskets and MFP. As we discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49509), beginning with the FY 2016 rulemaking cycle, the MFP adjustment is calculated using the revised series developed by IGI to proxy the aggregate capital inputs. Specifically, in order to generate a forecast of MFP, IGI forecasts BLS aggregate capital inputs using a regression model. A complete description of the MFP projection methodology is available on the CMS website at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html*.

For FY 2021, we are proposing an MFP adjustment of 0.4 percentage point. Similar to the market basket update, for this proposed rule, we used IGI's fourth quarter 2019 forecast of the MFP adjustment to compute the proposed FY 2021 MFP adjustment. As noted previously, we are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2021 market basket update and the MFP adjustment for the final rule.

Based on these data, for this proposed rule, we have determined four proposed applicable percentage increases to the standardized amount for FY 2021, as specified in the following table:

PROPOSED FY 2021 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS

FY 2021	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Proposed Market Basket Rate-of-Increase	3.0	3.0	3.0	3.0
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.75	-0.75
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-2.25	0	-2.25
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.4	-0.4	-0.4	-0.4
Proposed Applicable Percentage Increase Applicd to Standardizcd Amount	**2.6**	**0.35**	**1.85**	**-0.4**

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42344), we revised our regulations at 42 CFR 412.64(d) to reflect the current law for the update for FY 2020 and subsequent fiscal years. Specifically, in accordance with section 1886(b)(3)(B) of the Act, we added paragraph (d)(1)(viii) to § 412.64 to set forth the applicable percentage increase to the operating standardized amount for FY 2020 and subsequent fiscal years as the percentage increase in the market basket index, subject to the reductions specified under § 412.64(d)(2) for a hospital that does not submit quality data and § 412.64(d)(3) for a hospital that is not a meaningful EHR user, less an MFP adjustment. (As previously noted, section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.)

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital-specific rates for SCHs and MDHs also is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. (Under current law, the MDH program is effective for discharges on or before September 30, 2022, as discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41429 through 41430).)

For FY 2021, we are proposing the following updates to the hospital-specific rates applicable to SCHs and MDHs: A proposed update of 2.6 percent for a hospital that submits quality data and is a meaningful EHR user; a proposed update of 1.85 percent for a hospital that fails to submit quality data and is a meaningful EHR user; a proposed update of 0.35 percent for a hospital that submits quality data and is not a meaningful EHR user; and a proposed update of −0.4 percent for a hospital that fails to submit quality data and is not a meaningful EHR user. As noted previously, for this FY 2021 IPPS/LTCH PPS proposed rule, we are using IGI's fourth quarter 2019 forecast of the 2014-based IPPS market basket update with historical data through third quarter 2019. Similarly, we used IGI's fourth quarter 2019 forecast of the MFP adjustment. We are proposing that if more recent data subsequently become available (for example, a more recent estimate of the market basket increase and the MFP adjustment), we would use

such data, if appropriate, to determine the update in the final rule.

2. FY 2021 Puerto Rico Hospital Update

As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56937 through 56938), prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 601 of Public Law 114–113 amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to determine an update to the Puerto Rico standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the same update to the national standardized amount discussed under section IV.B.1. of the preamble of this proposed rule. Accordingly, in this FY 2021 IPPS/LTCH PPS proposed rule, for FY 2021, we are proposing an applicable percentage increase of 2.6 percent to the standardized amount for hospitals located in Puerto Rico.

We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.

In addition, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also to apply the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act to Puerto Rico hospitals that are not meaningful EHR users, effective FY 2022. Accordingly, because the provisions of section 1886(b)(3)(B)(ix) of the Act are not applicable to hospitals located in Puerto Rico until FY 2022, the adjustments under this provision are not applicable for FY 2021.

C. Proposed Amendment To Address Short Cost Reporting Periods During Applicable Timeframe for Establishment of Service Area for Sole Community Hospitals Under § 412.92(c)(3)

Sections 1886(d)(5)(D) and (d)(5)(G) of the Act provide special payment protections under the IPPS to sole community hospitals (SCHs) and Medicare-dependent, small rural hospitals (MDHs), respectively. Section 1886(d)(5)(D)(iii) of the Act defines an SCH in part as a hospital that the Secretary determines is located more than 35 road miles from another hospital or that, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of inpatient hospital services reasonably available to Medicare beneficiaries. The regulations at 42 CFR 412.92 set forth the criteria that a hospital must meet to be classified as a SCH. For more information on SCHs, we refer readers to the FY 2009 IPPS/LTCH PPS final rule (74 FR 43894 through 43897).

The criteria to be classified as an SCH are set forth at 42 CFR 412.92(a). Under the criteria at 42 CFR 412.92(a)(1)(i) and (ii), CMS classifies a hospital as a sole community hospital if it is located: (1) In a rural area; and (2) between 25 and 35 miles from other like hospitals and meets one of the following criteria:

- No more than 25 percent of residents who become hospital inpatients or no more than 25 percent of the Medicare beneficiaries who become hospital inpatients in the hospital's service area are admitted to other like hospitals located within a 35-mile radius of the hospital, or, if larger, within its service area.
- The hospital has fewer than 50 beds and the MAC certifies that the hospital would have met the previously discussed criteria were it not for the fact that some beneficiaries or residents were forced to seek care outside the service area due to the unavailability of necessary specialty services at the community hospital.

The term ''service area'' is defined under the regulations at 42 CFR 412.92(c)(3) as the area from which a hospital draws at least 75 percent of its inpatients during the most recent 12-month cost reporting period ending before it applies for classification as a sole community hospital. For more information on service areas, we refer readers to the FY 2002 IPPS final rule (66 FR 39875).

We have become aware of some situations where a hospital's most recent cost reporting period prior to seeking SCH classification is a short cost reporting period (that is, less than a 12-month cost reporting period). We are therefore proposing to amend § 412.92(c)(3) to clarify our policy in this situation. Specifically, we are proposing to amend § 412.92(c)(3) to reflect that where the hospital's cost reporting period ending before it applies for classification as a sole community hospital is for less than 12 months, the hospital's most recent 12-month or longer cost reporting period before the short period is used. We note that this policy is consistent with our policy for determining Medicare utilization for purposes of MDH classification, as reflected in the regulations at 42 CFR 412.108(a)(1)(v). We are inviting public comment on our proposed amendment to § 412.92(c)(3) to reflect our policy that if the hospital's most recent cost reporting period is shorter than 12 months, the next most recent cost reporting period is used to determine the service area for purposes of SCH classification, provided it is at least 12 months.

D. Rural Referral Centers (RRCs)—Proposed Annual Updates to Case-Mix Index and Discharge Criteria (§ 412.96)

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at § 412.96 set forth the criteria that a hospital must meet in order to qualify under the IPPS as a rural referral center (RRC). RRCs receive special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of Public Law 108–173 raised the DSH payment adjustment for RRCs such that they are not subject to the 12-percent cap on DSH payments that is applicable to other rural hospitals. RRCs also are not subject to the proximity criteria when applying for geographic reclassification. In addition, they do not have to meet the requirement that a hospital's average hourly wage must exceed, by a certain percentage, the average hourly wage of the labor market area in which the hospital is located.

Section 4202(b) of Public Law 105–33 states, in part, that any hospital classified as an RRC by the Secretary for FY 1991 shall be classified as such an RRC for FY 1998 and each subsequent fiscal year. In the August 29, 1997 IPPS final rule with comment period (62 FR 45999), we reinstated RRC status for all hospitals that lost that status due to triennial review or MGCRB reclassification. However, we did not reinstate the status of hospitals that lost RRC status because they were now

urban for all purposes because of the OMB designation of their geographic area as urban. Subsequently, in the August 1, 2000 IPPS final rule (65 FR 47089), we indicated that we were revisiting that decision. Specifically, we stated that we would permit hospitals that previously qualified as an RRC and lost their status due to OMB redesignation of the county in which they are located from rural to urban, to be reinstated as an RRC. Otherwise, a hospital seeking RRC status must satisfy all of the other applicable criteria. We use the definitions of ''urban'' and ''rural'' specified in subpart D of 42 CFR part 412. One of the criteria under which a hospital may qualify as an RRC is to have 275 or more beds available for use (§ 412.96(b)(1)(ii)). A rural hospital that does not meet the bed size requirement can qualify as an RRC if the hospital meets two mandatory prerequisites (a minimum case-mix index (CMI) and a minimum number of discharges), and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume). (We refer readers to § 412.96(c)(1) through (5) and the September 30, 1988 **Federal Register** (53 FR 38513) for additional discussion.) With respect to the two mandatory prerequisites, a hospital may be classified as an RRC if—

- The hospital's CMI is at least equal to the lower of the median CMI for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median CMI for all urban hospitals nationally; and
- The hospital's number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges per year, as specified in section 1886(d)(5)(C)(i) of the Act.

1. Case-Mix Index (CMI)

Section 412.96(c)(1) provides that CMS establish updated national and regional CMI values in each year's annual notice of prospective payment rates for purposes of determining RRC status. The methodology we used to determine the national and regional CMI values is set forth in the regulations at § 412.96(c)(1)(ii). The proposed national median CMI value for FY 2021 is based on the CMI values of all urban hospitals nationwide, and the proposed regional median CMI values for FY 2021 are based on the CMI values of all urban hospitals within each census region, excluding those hospitals with approved teaching programs (that is, those hospitals that train residents in an approved GME program as provided in § 413.75). These proposed values are based on discharges occurring during FY 2019 (October 1, 2018 through September 30, 2019), and include bills posted to CMS' records through December 2019.

In this FY 2021 IPPS/LTCH PPS proposed rule, we are proposing that, in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2020, they must have a CMI value for FY 2019 that is at least—

- 1.70435 (national—all urban); or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The proposed median CMI values by region are set forth in this table. We intend to update the proposed CMI values in the FY 2021 final rule to reflect the updated FY 2019 MedPAR file, which will contain data from additional bills received through March 2020.

Region	Proposed Case-Mix Index Value
1. New England (CT, ME, MA, NH, RI, VT)	1.4463
2. Middle Atlantic (PA, NJ, NY)	1.502
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.5777
4. East North Central (IL, IN, MI, OH, WI)	1.6117
5. East South Central (AL, KY, MS, TN)	1.5412
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.654
7. West South Central (AR, LA, OK, TX)	1.7495
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.7834
9. Pacific (AK, CA, HI, OR, WA)	1.6928

A hospital seeking to qualify as an RRC should obtain its hospital-specific CMI value (not transfer-adjusted) from its MAC. Data are available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, the CMI values are computed based on all Medicare patient discharges subject to the IPPS MS–DRG-based payment.

2. Discharges

Section 412.96(c)(2)(i) provides that CMS set forth the national and regional numbers of discharges criteria in each year's annual notice of prospective payment rates for purposes of determining RRC status. As specified in section 1886(d)(5)(C)(ii) of the Act, the national standard is set at 5,000 discharges. For FY 2021, we are proposing to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2018 (that is, October 1, 2017 through September 30, 2018), which are the latest cost report data available at the time this proposed rule was developed. Therefore, we are proposing that, in addition to meeting other criteria, a hospital, if it is to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2020, must have, as the number of discharges for its cost reporting period that began during FY 2018, at least—

- 5,000 (3,000 for an osteopathic hospital); or
- If less, the median number of discharges for urban hospitals in the census region in which the hospital is located. We refer readers to the proposed numbers of discharges as set forth in this table. We intend to update these numbers in the FY 2021 final rule based on the latest available cost report data.

Region	Proposed Number of Discharges
1. New England (CT, ME, MA, NH, RI, VT)	8,621
2. Middle Atlantic (PA, NJ, NY)	10,231
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	10,591
4. East North Central (IL, IN, MI, OH, WI)	8,609
5. East South Central (AL, KY, MS, TN)	9,067
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	7,647
7. West South Central (AR, LA, OK, TX)	6,001
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	8,988
9. Pacific (AK, CA, HI, OR, WA)	9,059

We note that because the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges, under this proposed rule, 5,000 discharges is the minimum criterion for all hospitals, except for osteopathic hospitals for which the minimum criterion is 3,000 discharges.

a. Proposed Amendment to § 412.96(c)(2) for Hospital Cost Reporting Periods That Are Longer or Shorter Than 12 Months

As previously noted, in addition to meeting other criteria, to qualify for initial RRC status for cost reporting periods beginning on or after October 1 of a given fiscal year, under § 412.96(c)(2), a hospital must meet the minimum number of discharges during its cost reporting period that began during the same fiscal year as the cost reporting periods used to compute the regional median discharges. We typically use the cost reporting periods that are 3 years prior to the fiscal year for which a hospital is seeking RRC status to compute the regional median discharges, as these are generally the latest cost report data available at the time of the development of the proposed and final rules. For example, and as discussed previously, for FY 2021, we are proposing to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2018.

We have become aware of situations where a hospital's cost reporting period that began during the fiscal year used to compute the regional median discharge values for a given fiscal year is a short cost reporting period (that is, less than 12 months) and as a result, the provider may not meet the minimum discharges requirement. Conversely, there may also be situations where a hospital's cost reporting period that began during the fiscal year used to compute the regional median discharge values for a given fiscal year is a long cost reporting period (that is, greater than 12 months). We are proposing to amend the RRC regulations to add a new paragraph (c)(2)(iii) to § 412.96 stating that if the hospital's cost reporting period that began during the same fiscal year as the cost reporting periods used to compute the regional median discharges is for less than 12 months or longer than 12 months, the hospital's number of discharges for that cost reporting period will be annualized to estimate the total number of discharges for a 12 month cost reporting period. We believe this policy, which is generally consistent with how we have addressed short cost reporting periods for purposes of determining discharges for RRC status in the past, provides a more level playing field for purposes of determining the number of discharges for those hospitals for which the applicable cost reporting period is shorter or longer than 12 months. We are proposing that to annualize the discharges, the MAC would divide the discharges by the number of days in the hospital's cost reporting period and then multiply by the length of a full year (365 or 366 calendar days, as applicable) to estimate the total number of discharges for a 12-month cost reporting period. For example, a short cost reporting period beginning on January 1 and ending on October 31 that is 10 months (or 304 days) with 4,200 discharges would be annualized in a non-leap year as follows: $(4{,}200 \div 304) \times 365 = 5{,}043$ discharges annualized. Under this proposal, if the hospital has multiple cost reports beginning in the same fiscal year and none of those cost reports are for 12 months, the hospital's number of discharges in the hospital's longest cost report beginning in that fiscal year would be annualized to estimate the total number of discharges for a 12 month cost reporting period. We are inviting public comment on our proposed annualization methodology and our proposed amendment to § 412.96(c)(2).

E. Proposed Payment Adjustment for Low-Volume Hospitals (§ 412.101)

1. Background

Section 1886(d)(12) of the Act provides for an additional payment to each qualifying low-volume hospital under the IPPS beginning in FY 2005. The additional payment adjustment to a low-volume hospital provided for under section 1886(d)(12) of the Act is in addition to any payment calculated under section 1886 of the Act. Therefore, the additional payment adjustment is based on the per discharge amount paid to the qualifying hospital under section 1886 of the Act. In other words, the low-volume hospital payment adjustment is based on total per discharge payments made under section 1886 of the Act, including capital, DSH, IME, and outlier payments. For SCHs and MDHs, the low-volume hospital payment adjustment is based in part on either the Federal rate or the hospital-specific rate, whichever results in a greater operating IPPS payment.

As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41398 through 41399), section 50204 of the

Bipartisan Budget Act of 2018 (Pub. L. 115–123) modified the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals for FYs 2019 through 2022. (Section 50204 also extended prior changes to the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals through FY 2018.) Currently, the low-volume hospital qualifying criteria provide that a hospital must have fewer 3,800 total discharges during the fiscal year, and the hospital must be located more than 15 road miles from the nearest ''subsection (d)'' hospital. These criteria will remain in effect through FY 2022. Beginning with FY 2023, the low-volume hospital qualifying criteria and payment adjustment will revert to the statutory requirements that were in effect prior to FY 2011. Therefore, in order for a hospital to continue to qualify as a low-volume hospital on or after October 1, 2022, it must have fewer 200 total discharges during the fiscal year and be located more than 25 road miles from the nearest ''subsection (d)'' hospital (see § 412.101(b)(2)(i)). (For additional information on the low-volume hospital payment adjustment prior to FY 2018, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56941 through 56943). For additional information on the low-volume hospital payment adjustment for FY 2018, we refer readers to the FY 2018 IPPS notice (CMS–1677–N) that appeared in the **Federal Register** on April 26, 2018 (83 FR 18301 through 18308).)

2. Temporary Changes to the Low-Volume Hospital Definition and Payment Adjustment Methodology for FYs 2019 Through 2022

As discussed earlier, section 50204 of the Bipartisan Budget Act of 2018 further modified the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals for FYs 2019 through 2022. Specifically, the qualifying criteria for low-volume hospitals under section 1886(d)(12)(C)(i) of the Act were amended to specify that, for FYs 2019 through 2022, a subsection (d) hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 3,800 total discharges during the fiscal year. Section 1886(d)(12)(D) of the Act was also amended to provide that, for discharges occurring in FYs 2019 through 2022, the Secretary shall determine the applicable percentage increase using a continuous, linear sliding scale ranging from an additional 25 percent payment adjustment for low-volume hospitals with 500 or fewer discharges to a zero percent additional payment for low-volume hospitals with more than 3,800 discharges in the fiscal year. Consistent with the requirements of section 1886(d)(12)(C)(ii) of the Act, the term ''discharge'' for purposes of these provisions refers to total discharges, regardless of payer (that is, Medicare and non-Medicare discharges).

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399), to implement this requirement, we specified a continuous, linear sliding scale formula to determine the low-volume hospital payment adjustment for FYs 2019 through 2022 that is similar to the continuous, linear sliding scale formula used to determine the low-volume hospital payment adjustment originally established by the Affordable Care Act and implemented in the regulations at § 412.101(c)(2)(ii) in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50240 through 50241). Consistent with the statute, we provided that qualifying hospitals with 500 or fewer total discharges will receive a low-volume hospital payment adjustment of 25 percent. For qualifying hospitals with fewer than 3,800 discharges but more than 500 discharges, the low-volume payment adjustment is calculated by subtracting from 25 percent the proportion of payments associated with the discharges in excess of 500. As such, for qualifying hospitals with fewer than 3,800 total discharges but more than 500 total discharges, the low-volume hospital payment adjustment for FYs 2019 through 2022 is calculated using the following formula:

Low-Volume Hospital Payment Adjustment = $0.25 - [0.25 / 3{,}300] \times$ (number of total discharges $- 500$) = $(95 / 330) -$ (number of total discharges / 13,200).

For this purpose, we specified that the ''number of total discharges'' is determined as total discharges, which includes Medicare and non-Medicare discharges during the fiscal year, based on the hospital's most recently submitted cost report. The low-volume hospital payment adjustment for FYs 2019 through 2022 is set forth in the regulations at 42 CFR 412.101(c)(3).

3. Process for Requesting and Obtaining the Low-Volume Hospital Payment Adjustment

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414) and subsequent rulemaking (for example, the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 through 41401), we discussed the process for requesting and obtaining the low-volume hospital payment adjustment. Under this previously established process, a hospital makes a written request for the low-volume payment adjustment under § 412.101 to its MAC. This request must contain sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria. The MAC will determine if the hospital qualifies as a low-volume hospital by reviewing the data the hospital submits with its request for low-volume hospital status in addition to other available data. Under this approach, a hospital will know in advance whether or not it will receive a payment adjustment under the low-volume hospital policy. The MAC and CMS may review available data such as the number of discharges, in addition to the data the hospital submits with its request for low-volume hospital status, in order to determine whether or not the hospital meets the qualifying criteria. (For additional information on our existing process for requesting the low-volume hospital payment adjustment, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 through 41401).)

As explained earlier, for FY 2019 and subsequent fiscal years, the discharge determination is made based on the hospital's number of total discharges, that is, Medicare and non-Medicare discharges, as was the case for FYs 2005 through 2010. Under § 412.101(b)(2)(i) and § 412.101(b)(2)(iii), a hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume payment adjustment in the current year. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 and 41400), we use cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. (For FYs 2011 through 2018, the most recently available MedPAR data were used to determine the hospital's Medicare discharges because non-Medicare discharges were not used to determine if a hospital met the discharge criterion for those years.) Therefore, a hospital should refer to its most recently submitted cost report for total discharges (Medicare and non-Medicare) in order to decide whether or not to apply for low-volume hospital status for a particular fiscal year.

As also discussed in the FY 2019 IPPS/LTCH PPS final rule, in addition to the discharge criterion, for FY 2019

and for subsequent fiscal years, eligibility for the low-volume hospital payment adjustment is also dependent upon the hospital meeting the applicable mileage criterion specified in § 412.101(b)(2)(i) or (iii) for the fiscal year. Specifically, to meet the mileage criterion to qualify for the low-volume hospital payment adjustment for FY 2021, as was the case for FYs 2019 and 2020, a hospital must be located more than 15 road miles from the nearest subsection (d) hospital. (We define in § 412.101(a) the term ''road miles'' to mean ''miles'' as defined in § 412.92(c)(1) (75 FR 50238 through 50275 and 50414).) For establishing that the hospital meets the mileage criterion, the use of a web-based mapping tool as part of the documentation is acceptable. The MAC will determine if the information submitted by the hospital, such as the name and street address of the nearest hospitals, location on a map, and distance from the hospital requesting low-volume hospital status, is sufficient to document that it meets the mileage criterion. If not, the MAC will follow up with the hospital to obtain additional necessary information to determine whether or not the hospital meets the applicable mileage criterion.

In accordance with our previously established process, a hospital must make a written request for low-volume hospital status that is received by its MAC by September 1 immediately preceding the start of the Federal fiscal year for which the hospital is applying for low-volume hospital status in order for the applicable low-volume hospital payment adjustment to be applied to payments for its discharges for the fiscal year beginning on or after October 1 immediately following the request (that is, the start of the Federal fiscal year). For a hospital whose request for low-volume hospital status is received after September 1, if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the applicable low-volume hospital payment adjustment to determine payment for the hospital's discharges for the fiscal year, effective prospectively within 30 days of the date of the MAC's low-volume status determination.

Consistent with this previously established process, for FY 2021, we are proposing that a hospital must submit a written request for low-volume hospital status to its MAC that includes sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria (as described earlier). Consistent with historical practice, for FY 2021, we are proposing that a hospital's written request must be received by its MAC no later than September 1, 2020 in order for the low-volume hospital payment adjustment to be applied to payments for its discharges beginning on or after October 1, 2020. If a hospital's written request for low-volume hospital status for FY 2021 is received after September 1, 2020, and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC would apply the low-volume hospital payment adjustment to determine the payment for the hospital's FY 2021 discharges, effective prospectively within 30 days of the date of the MAC's low-volume hospital status determination. We note that this proposal is consistent with the process for requesting and obtaining the low-volume hospital payment adjustment for FY 2020 (84 FR 42348 through 42349).

Under this process, a hospital receiving the low-volume hospital payment adjustment for FY 2020 may continue to receive a low-volume hospital payment adjustment for FY 2021 without reapplying if it continues to meet the applicable mileage and discharge criteria (which, as discussed previously, are the same qualifying criteria that apply for FY 2020). In this case, a hospital's request can include a verification statement that it continues to meet the mileage criterion applicable for FY 2021. (Determination of meeting the discharge criterion is discussed earlier in this section.) We note that a hospital must continue to meet the applicable qualifying criteria as a low-volume hospital (that is, the hospital must meet the applicable discharge criterion and mileage criterion for the fiscal year) in order to receive the payment adjustment in that fiscal year; that is, low-volume hospital status is not based on a ''one-time'' qualification (75 FR 50238 through 50275). Consistent with historical policy, a hospital must submit its request, including this written verification, for each fiscal year for which it seeks to receive the low-volume hospital payment adjustment, and in accordance with the timeline described earlier.

F. Indirect Medical Education (IME) Payment Adjustment Factor (§ 412.105)

Under the IPPS, an additional payment amount is made to hospitals with residents in an approved graduate medical education (GME) program in order to reflect the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The payment amount is determined by use of a statutorily specified adjustment factor. The regulations regarding the calculation of this additional payment, known as the IME adjustment, are located at § 412.105. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51680) for a full discussion of the IME adjustment and IME adjustment factor. Section 1886(d)(5)(B)(ii)(XII) of the Act provides that, for discharges occurring during FY 2008 and fiscal years thereafter, the IME formula multiplier is 1.35. Accordingly, for discharges occurring during FY 2021, the formula multiplier is 1.35. We estimate that application of this formula multiplier for the FY 2021 IME adjustment will result in an increase in IPPS payment of 5.5 percent for every approximately 10 percent increase in the hospital's resident-to-bed ratio.

G. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2021 (§ 412.106)

1. General Discussion

Section 1886(d)(5)(F) of the Act provides for additional Medicare payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. The Act specifies two methods by which a hospital may qualify for the Medicare disproportionate share hospital (DSH) adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to needy patients with low incomes. This method is commonly referred to as the ''Pickle method.'' The second method for qualifying for the DSH payment adjustment, which is the most common, is based on a complex statutory formula under which the DSH payment adjustment is based on the hospital's geographic designation, the number of beds in the hospital, and the level of the hospital's disproportionate patient percentage (DPP). A hospital's DPP is the sum of two fractions: the ''Medicare fraction'' and the ''Medicaid fraction.'' The Medicare fraction (also known as the ''SSI fraction'' or ''SSI ratio'') is computed by dividing the number of the hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients

who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days in the same period.

Because the DSH payment adjustment is part of the IPPS, the statutory references to ''days'' in section 1886(d)(5)(F) of the Act have been interpreted to apply only to hospital acute care inpatient days. Regulations located at 42 CFR 412.106 govern the Medicare DSH payment adjustment and specify how the DPP is calculated as well as how beds and patient days are counted in determining the Medicare DSH payment adjustment. Under § 412.106(a)(1)(i), the number of beds for the Medicare DSH payment adjustment is determined in accordance with bed counting rules for the IME adjustment under § 412.105(b).

Section 3133 of the Patient Protection and Affordable Care Act, as amended by section 10316 of the same Act and section 1104 of the Health Care and Education Reconciliation Act (Pub. L. 111–152), added a section 1886(r) to the Act that modifies the methodology for computing the Medicare DSH payment adjustment. (For purposes of this proposed rule, we refer to these provisions collectively as section 3133 of the Affordable Care Act.) Beginning with discharges in FY 2014, hospitals that qualify for Medicare DSH payments under section 1886(d)(5)(F) of the Act receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments. This provision applies equally to hospitals that qualify for DSH payments under section 1886(d)(5)(F)(i)(I) of the Act and those hospitals that qualify under the Pickle method under section 1886(d)(5)(F)(i)(II) of the Act.

The remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured, is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The payments to each hospital for a fiscal year are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all hospitals that receive Medicare DSH payments for that fiscal year.

As provided by section 3133 of the Affordable Care Act, section 1886(r) of the Act requires that, for FY 2014 and each subsequent fiscal year, a subsection (d) hospital that would otherwise receive DSH payments made under section 1886(d)(5)(F) of the Act receives two separately calculated payments. Specifically, section 1886(r)(1) of the Act provides that the Secretary shall pay to such subsection (d) hospital (including a Pickle hospital) 25 percent of the amount the hospital would have received under section 1886(d)(5)(F) of the Act for DSH payments, which represents the empirically justified amount for such payment, as determined by the MedPAC in its March 2007 Report to Congress. We refer to this payment as the ''empirically justified Medicare DSH payment.''

In addition to this empirically justified Medicare DSH payment, section 1886(r)(2) of the Act provides that, for FY 2014 and each subsequent fiscal year, the Secretary shall pay to such subsection (d) hospital an additional amount equal to the product of three factors. The first factor is the difference between the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if subsection (r) did not apply and the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year. Therefore, this factor amounts to 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act.

The second factor is, for FY 2018 and subsequent fiscal years, 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS), and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified), minus 0.2 percentage point for FYs 2018 and 2019.

The third factor is a percent that, for each subsection (d) hospital, represents the quotient of the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data), including the use of alternative data where the Secretary determines that alternative data are available which are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, and the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act. Therefore, this third factor represents a hospital's uncompensated care amount for a given time period relative to the uncompensated care amount for that same time period for all hospitals that receive Medicare DSH payments in the applicable fiscal year, expressed as a percent.

For each hospital, the product of these three factors represents its additional payment for uncompensated care for the applicable fiscal year. We refer to the additional payment determined by these factors as the ''uncompensated care payment.''

Section 1886(r) of the Act applies to FY 2014 and each subsequent fiscal year. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50620 through 50647) and the FY 2014 IPPS interim final rule with comment period (78 FR 61191 through 61197), we set forth our policies for implementing the required changes to the Medicare DSH payment methodology made by section 3133 of the Affordable Care Act for FY 2014. In those rules, we noted that, because section 1886(r) of the Act modifies the payment required under section 1886(d)(5)(F) of the Act, it affects only the DSH payment under the operating IPPS. It does not revise or replace the capital IPPS DSH payment provided under the regulations at 42 CFR part 412, subpart M, which were established through the exercise of the Secretary's discretion in implementing the capital IPPS under section 1886(g)(1)(A) of the Act.

Finally, section 1886(r)(3) of the Act provides that there shall be no administrative or judicial review under section 1869, section 1878, or otherwise of any estimate of the Secretary for purposes of determining the factors described in section 1886(r)(2) of the Act or of any period selected by the Secretary for the purpose of determining those factors. Therefore, there is no administrative or judicial review of the estimates developed for purposes of applying the three factors used to determine uncompensated care payments, or the periods selected in order to develop such estimates.

2. Eligibility for Empirically Justified Medicare DSH Payments and Uncompensated Care Payments

As explained earlier, the payment methodology under section 3133 of the Affordable Care Act applies to ''subsection (d) hospitals'' that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act. Therefore, hospitals must receive empirically justified Medicare DSH payments in a fiscal year in order to receive an additional Medicare uncompensated care payment for that

year. Specifically, section 1886(r)(2) of the Act states that, in addition to the payment made to a subsection (d) hospital under section 1886(r)(1) of the Act, the Secretary shall pay to such subsection (d) hospitals an additional amount. Because section 1886(r)(1) of the Act refers to empirically justified Medicare DSH payments, the additional payment under section 1886(r)(2) of the Act is limited to hospitals that receive empirically justified Medicare DSH payments in accordance with section 1886(r)(1) of the Act for the applicable fiscal year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and the FY 2014 IPPS interim final rule with comment period (78 FR 61193), we provided that hospitals that are not eligible to receive empirically justified Medicare DSH payments in a fiscal year will not receive uncompensated care payments for that year. We also specified that we would make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available). We indicated that our final determination on the hospital's eligibility for uncompensated care payments will be based on the hospital's actual DSH status at cost report settlement for that payment year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and in the rulemaking for subsequent fiscal years, we have specified our policies for several specific classes of hospitals within the scope of section 1886(r) of the Act. In this FY 2021 IPPS/LTCH PPS proposed rule), we discuss our specific policies regarding eligibility to receive empirically justified Medicare DSH payments and uncompensated care payments for FY 2021 with respect to the following hospitals:

- *Subsection (d) Puerto Rico hospitals* that are eligible for DSH payments also are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the new payment methodology (78 FR 50623 and 79 FR 50006).
- *Maryland hospitals* are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the payment methodology of section 1886(r) of the Act because they are not paid under the IPPS. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41402 through 41403), CMS and the State have entered into an agreement to govern payments to Maryland hospitals under a new payment model, the Maryland Total Cost of Care (TCOC) Model, which began on January 1, 2019. Under the Maryland TCOC Model, Maryland hospitals will not be paid under the IPPS in FY 2021, and will be ineligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act.
- *Sole community hospitals (SCHs) that are paid under their hospital-specific rate* are not eligible for Medicare DSH payments. SCHs that are paid under the IPPS Federal rate receive interim payments based on what we estimate and project their DSH status to be prior to the beginning of the Federal fiscal year (based on the best available data at that time) subject to settlement through the cost report, and if they receive interim empirically justified Medicare DSH payments in a fiscal year, they also will receive interim uncompensated care payments for that fiscal year on a per discharge basis, subject as well to settlement through the cost report. Final eligibility determinations will be made at the end of the cost reporting period at settlement, and both interim empirically justified Medicare DSH payments and uncompensated care payments will be adjusted accordingly (78 FR 50624 and 79 FR 50007).
- *Medicare-dependent, small rural hospitals (MDHs)* are paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years (76 FR 51684). The IPPS Federal rate that is used in the MDH payment methodology is the same IPPS Federal rate that is used in the SCH payment methodology. Section 50205 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), enacted on February 9, 2018, extended the MDH program for discharges on or after October 1, 2017, through September 30, 2022. Because MDHs are paid based on the IPPS Federal rate, they continue to be eligible to receive empirically justified Medicare DSH payments and uncompensated care payments if their DPP is at least 15 percent, and we apply the same process to determine MDHs' eligibility for empirically justified Medicare DSH and uncompensated care payments as we do for all other IPPS hospitals. Due to the extension of the MDH program, MDHs will continue to be paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years. Accordingly, we will continue to make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available). Our final determination on the hospital's eligibility for uncompensated care payments will be based on the hospital's actual DSH status at cost report settlement for that payment year. In addition, as we do for all IPPS hospitals, we will calculate a Factor 3 and an uncompensated care payment amount for all MDHs, regardless of whether they are projected to be eligible for Medicare DSH payments during the fiscal year, but the denominator of Factor 3 of the uncompensated care payment methodology will be based only on the uncompensated care data from the hospitals that we have projected to be eligible for Medicare DSH payments during the fiscal year.
- *IPPS hospitals that elect to participate in the Bundled Payments for Care Improvement Advanced Initiative (BPCI Advanced) model starting October 1, 2018,* will continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. For further information regarding the BPCI Advanced model, we refer readers to the CMS website at: *https://innovation.cms.gov/initiatives/bpci-advanced/*.
- *IPPS hospitals that are participating in the Comprehensive Care for Joint Replacement Model* (80 FR 73300) continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments.
- *Hospitals participating in the Rural Community Hospital Demonstration Program* are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act because they are not paid under the IPPS (78 FR 50625 and 79 FR 50008). The Rural Community Hospital Demonstration Program was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 114–255). The period of performance for this 5-year extension period ended December 31, 2016. Section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted December 13, 2016, again amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act),

therefore requiring an additional 5-year participation period for the demonstration program. Section 15003 of Public Law 114–255 also required a solicitation for applications for additional hospitals to participate in the demonstration program. At the time of issuance of this proposed rule, there are 27 hospitals participating in the demonstration program. Under the payment methodology that applies during the second 5 years of the extension period under the demonstration program, participating hospitals do not receive empirically justified Medicare DSH payments, and they are also excluded from receiving interim and final uncompensated care payments.

3. Empirically Justified Medicare DSH Payments

As we have discussed earlier, section 1886(r)(1) of the Act requires the Secretary to pay 25 percent of the amount of the Medicare DSH payment that would otherwise be made under section 1886(d)(5)(F) of the Act to a subsection (d) hospital. Because section 1886(r)(1) of the Act merely requires the program to pay a designated percentage of these payments, without revising the criteria governing eligibility for DSH payments or the underlying payment methodology, we stated in the FY 2014 IPPS/LTCH PPS final rule that we did not believe that it was necessary to develop any new operational mechanisms for making such payments. Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50626), we implemented this provision by advising MACs to simply adjust the interim claim payments to the requisite 25 percent of what would have otherwise been paid. We also made corresponding changes to the hospital cost report so that these empirically justified Medicare DSH payments can be settled at the appropriate level at the time of cost report settlement. We provided more detailed operational instructions and cost report instructions following issuance of the FY 2014 IPPS/LTCH PPS final rule that are available on the CMS website at: *http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R5P240.html*.

4. Uncompensated Care Payments

As we discussed earlier, section 1886(r)(2) of the Act provides that, for each eligible hospital in FY 2014 and subsequent years, the uncompensated care payment is the product of three factors. These three factors represent our estimate of 75 percent of the amount of Medicare DSH payments that would otherwise have been paid, an adjustment to this amount for the percent change in the national rate of uninsurance compared to the rate of uninsurance in 2013, and each eligible hospital's estimated uncompensated care amount relative to the estimated uncompensated care amount for all eligible hospitals. In this section of this proposed rule, we discuss the data sources and methodologies for computing each of these factors, our final policies for FYs 2014 through 2020, and our proposed policies for FY 2021.

a. Proposed Calculation of Factor 1 for FY 2021

Section 1886(r)(2)(A) of the Act establishes Factor 1 in the calculation of the uncompensated care payment. Section 1886(r)(2)(A) of the Act states that this factor is equal to the difference between: (1) The aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year (as estimated by the Secretary); and (2) the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year (as so estimated). Therefore, section 1886(r)(2)(A)(i) of the Act represents the estimated Medicare DSH payments that would have been made under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year. Under a prospective payment system, we would not know the precise aggregate Medicare DSH payment amount that would be paid for a Federal fiscal year until cost report settlement for all IPPS hospitals is completed, which occurs several years after the end of the Federal fiscal year. Therefore, section 1886(r)(2)(A)(i) of the Act provides authority to estimate this amount, by specifying that, for each fiscal year to which the provision applies, such amount is to be estimated by the Secretary. Similarly, section 1886(r)(2)(A)(ii) of the Act represents the estimated empirically justified Medicare DSH payments to be made in a fiscal year, as prescribed under section 1886(r)(1) of the Act. Again, section 1886(r)(2)(A)(ii) of the Act provides authority to estimate this amount.

Therefore, Factor 1 is the difference between our estimates of: (1) The amount that would have been paid in Medicare DSH payments for the fiscal year, in the absence of the new payment provision; and (2) the amount of empirically justified Medicare DSH payments that are made for the fiscal year, which takes into account the requirement to pay 25 percent of what would have otherwise been paid under section 1886(d)(5)(F) of the Act. In other words, this factor represents our estimate of 75 percent (100 percent minus 25 percent) of our estimate of Medicare DSH payments that would otherwise be made, in the absence of section 1886(r) of the Act, for the fiscal year.

As we did for FY 2020, in this FY 2021 IPPS/LTCH PPS proposed rule, in order to determine Factor 1 in the uncompensated care payment formula for FY 2021, we are proposing to continue the policy established in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50628 through 50630) and in the FY 2014 IPPS interim final rule with comment period (78 FR 61194) of determining Factor 1 by developing estimates of both the aggregate amount of Medicare DSH payments that would be made in the absence of section 1886(r)(1) of the Act and the aggregate amount of empirically justified Medicare DSH payments to hospitals under 1886(r)(1) of the Act. Consistent with the policy that has applied in previous years, these estimates will not be revised or updated subsequent to the publication of our final projections in the FY 2021 IPPS/LTCH PPS final rule.

Therefore, in order to determine the two elements of proposed Factor 1 for FY 2021 (Medicare DSH payments prior to the application of section 1886(r)(1) of the Act, and empirically justified Medicare DSH payments after application of section 1886(r)(1) of the Act), for this proposed rule, we used the most recently available projections of Medicare DSH payments for the fiscal year, as calculated by CMS' Office of the Actuary using the most recently filed Medicare hospital cost reports with Medicare DSH payment information and the most recent Medicare DSH patient percentages and Medicare DSH payment adjustments provided in the IPPS Impact File. The determination of the amount of DSH payments is partially based on the Office of the Actuary's Part A benefits projection model. One of the results of this model is inpatient hospital spending. Projections of DSH payments require projections for expected increases in utilization and case-mix. The assumptions that were used in making these projections and the resulting estimates of DSH payments for FY 2018 through FY 2021 are discussed in the table titled ''Factors Applied for FY 2018 through FY 2021 to Estimate Medicare DSH Expenditures Using FY 2017 Baseline.''

For purposes of calculating Factor 1 and modeling the impact of this FY 2021 IPPS/LTCH PPS proposed rule, we

used the Office of the Actuary's December 2019 Medicare DSH estimates, which were based on data from the September 2019 update of the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2020 IPPS/LTCH PPS final rule IPPS Impact File, published in conjunction with the publication of the FY 2020 IPPS/LTCH PPS final rule. Because SCHs that are projected to be paid under their hospital-specific rate are excluded from the application of section 1886(r) of the Act, these hospitals also were excluded from the December 2019 Medicare DSH estimates. Furthermore, because section 1886(r) of the Act specifies that the uncompensated care payment is in addition to the empirically justified Medicare DSH payment (25 percent of DSH payments that would be made without regard to section 1886(r) of the Act), Maryland hospitals, which are not eligible to receive DSH payments, were also excluded from the Office of the Actuary's December 2019 Medicare DSH estimates. The 27 hospitals that are participating in the Rural Community Hospital Demonstration Program were also excluded from these estimates because, under the payment methodology that applies during the second 5 years of the extension period, these hospitals are not eligible to receive empirically justified Medicare DSH payments or interim and final uncompensated care payments.

For this proposed rule, using the data sources as previously discussed, the Office of the Actuary's December 2019 estimate for Medicare DSH payments for FY 2021 without regard to the application of section 1886(r)(1) of the Act, is approximately $14.004 billion. Therefore, also based on the December 2019 estimate, the estimate of empirically justified Medicare DSH payments for FY 2021, with the application of section 1886(r)(1) of the Act, is approximately $3.840 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2021). Under § 412.106(g)(1)(i) of the regulations, Factor 1 is the difference between these two estimates of the Office of the Actuary. Therefore, in this proposed rule, we are proposing that Factor 1 for FY 2021 would be $11,518,901,035.84, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2021 ($15,358,534,714.46 minus $3,839,633,678.61). We note that consistent with our approach in previous rulemakings, OACT intends to use more recent data that may become available for purposes of projecting the final Factor 1 estimates for the FY 2021 IPPS/LTCH PPS final rule.

The Factor 1 estimates for proposed rules are generally consistent with the economic assumptions and actuarial analysis used to develop the President's Budget estimates under current law, and the Factor 1 estimates for the final rule are generally consistent with those used for the Midsession Review of the President's Budget. As we have in the past, for additional information on the development of the President's Budget, we refer readers to the Office of Management and Budget website at: *https://www.whitehouse.gov/omb/budget*. We recognize that our reliance on the economic assumptions and actuarial analysis used to develop the President's Budget in estimating Factor 1 has an impact on stakeholders who wish to replicate the Factor 1 calculation, such as modelling the relevant Medicare Part A portion of the budget, but we believe commenters are able to meaningfully comment on our proposed estimate of Factor 1 without replicating the President's Budget.

For a general overview of the principal steps involved in projecting future inpatient costs and utilization, we refer readers to the ''2019 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds'' available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/index.html?redirect=/reportstrustfunds/* under ''Downloads.'' We note that the annual reports of the Medicare Boards of Trustees to Congress represent the Federal Government's official evaluation of the financial status of the Medicare Program. The actuarial projections contained in these reports are based on numerous assumptions regarding future trends in program enrollment, utilization and costs of health care services covered by Medicare, as well as other factors affecting program expenditures. In addition, although the methods used to estimate future costs based on these assumptions are complex, they are subject to periodic review by independent experts to ensure their validity and reasonableness.

We also refer readers to the 2017 Actuarial Report on the Financial Outlook for Medicaid for a discussion of general issues regarding Medicaid projections. (available at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/MedicaidReport*).

In this proposed rule, we include information regarding the data sources, methods, and assumptions employed by the actuaries in determining the OACT's estimate of Factor 1. In summary, we indicate the historical HCRIS data update OACT used to identify Medicare DSH payments, we explain that the most recent Medicare DSH payment adjustments provided in the IPPS Impact File were used, and we provide the components of all the update factors that were applied to the historical data to estimate the Medicare DSH payments for the upcoming fiscal year, along with the associated rationale and assumptions. This discussion also includes a description of the ''Other'' and ''Discharges'' assumptions, and also provides additional information regarding how we address the Medicaid and CHIP expansion.

The Office of the Actuary's estimates for FY 2021 for this proposed rule began with a baseline of $14.004 billion in Medicare DSH expenditures for FY 2017. The following table shows the factors applied to update this baseline through the current estimate for FY 2021:

Factors Applied for FY 2018 through FY 2021 to Estimate Medicare DSH Expenditures Using FY 2017 Baseline						
FY	Update	Discharges	Case-Mix	Other	Total	Estimated DSH Payment (in billions)*
2018	1.018088	0.983	1.018	1.03145	1.0508	14.716
2019	1.0185	0.9549	1.01	1.02025	1.0022	14.748
2020	1.031	0.9756	1.005	0.9961	1.0069	14.850
2021	1.031	0.9959	1.005	1.00225	1.0342	15.359

*Rounded.

In this table, the discharges column shows the increase in the number of Medicare fee-for-service (FFS) inpatient hospital discharges. The figures for FY 2018 are based on Medicare claims data that have been adjusted by a completion factor to account for incomplete claims data. The discharge figure for FY 2019 is based on preliminary data for 2019. The discharge figures for FY 2020 and FY 2021 are assumptions based on recent trends recovering back to the long-term trend and assumptions related to how many beneficiaries will be enrolled in Medicare Advantage (MA) plans. The case-mix column shows the increase in case-mix for IPPS hospitals. The case-mix figures for FY 2018 and FY 2019 are based on actual data adjusted by a completion factor. The FY 2020 and FY 2021 increases are estimates based on the recommendation of the 2010–2011 Medicare Technical Review Panel. The ''Other'' column shows the increase in other factors that contribute to the Medicare DSH estimates. These factors include the difference between the total inpatient hospital discharges and the IPPS discharges, and various adjustments to the payment rates that have been included over the years but are not reflected in the other columns (such as the change in rates for the 2-midnight stay policy). In addition, the ''Other'' column includes a factor for the Medicaid expansion due to the Affordable Care Act. The factor for Medicaid expansion was developed using public information and statements for each State regarding its intent to implement the expansion. Based on this information, it is assumed that 55 percent of all individuals who were potentially newly eligible Medicaid enrollees in 2018 resided in States that had elected to expand Medicaid eligibility and, for 2020 and thereafter, that 58 percent of such individuals would reside in expansion States. In the future, these assumptions may change based on actual participation by States. For a discussion of general issues regarding Medicaid projections, we refer readers to the 2017 Actuarial Report on the Financial Outlook for Medicaid, which is available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/MedicaidReport2017.pdf*. We note that, in developing their estimates of the effect of Medicaid expansion on Medicare DSH expenditures, our actuaries have assumed that the new Medicaid enrollees are healthier than the average Medicaid recipient and, therefore, use fewer hospital services. Specifically, based on data from the President's Budget, the OACT assumed per capita spending for Medicaid beneficiaries who enrolled due to the expansion to be 50 percent of the average per capita expenditures for a pre-expansion Medicaid beneficiary due to the better health of these beneficiaries. This assumption is consistent with recent internal estimates of Medicaid per capita spending pre-expansion and post-expansion.

The following table shows the factors that are included in the ''Update'' column of the previous table:

FY	Market Basket Percentage	Affordable Care Act Payment Reductions	Multifactor Productivity Adjustment	Documentation and Coding	Total Update Percentage
2018	2.7	-0.75	-0.6	0.4588	1.8088
2019	2.9	-0.75	-0.8	0.5	1.85
2020	3.0	0	-0.4	0.5	3.1
2021	3.0	0	-0.4	0.5	3.1

Note: All numbers are based on the FY 2021 President's Budget projections, except for the FY 2021 percentages, which are based on the most recent forecast. We refer readers to section IV.B. of the preamble of this proposed rule for a complete discussion of the proposed changes in the inpatient hospital update for FY 2021.

b. Calculation of Proposed Factor 2 for FY 2021

(1) Background

Section 1886(r)(2)(B) of the Act establishes Factor 2 in the calculation of the uncompensated care payment. Section 1886(r)(2)(B)(ii) of the Act provides that, for FY 2018 and subsequent fiscal years, the second factor is 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS)

and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified), minus 0.2 percentage point for FYs 2018 and 2019. In FY 2020 and subsequent fiscal years, there is no longer a reduction. We note that, unlike section 1886(r)(2)(B)(i) of the Act, which governed the calculation of Factor 2 for FYs 2014, 2015, 2016, and 2017, section 1886(r)(2)(B)(ii) of the Act permits the use of a data source other than the CBO estimates to determine the percent change in the rate of uninsurance beginning in FY 2018. In addition, for FY 2018 and subsequent years, the statute does not require that the estimate of the percent of individuals who are uninsured be limited to individuals who are under 65 years of age.

As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38197), in our analysis of a potential data source for the rate of uninsurance for purposes of computing Factor 2 in FY 2018, we considered the following: (a) The extent to which the source accounted for the full U.S. population; (b) the extent to which the source comprehensively accounted for both public and private health insurance coverage in deriving its estimates of the number of uninsured; (c) the extent to which the source utilized data from the Census Bureau; (d) the timeliness of the estimates; (e) the continuity of the estimates over time; (f) the accuracy of the estimates; and (g) the availability of projections (including the availability of projections using an established estimation methodology that would allow for calculation of the rate of uninsurance for the applicable Federal fiscal year). As we explained in the FY 2018 IPPS/LTCH PPS final rule, these considerations are consistent with the statutory requirement that this estimate be based on data from the Census Bureau or other sources the Secretary determines appropriate and help to ensure the data source will provide reasonable estimates for the rate of uninsurance that are available in conjunction with the IPPS rulemaking cycle. We are proposing to use the same methodology as was used in FY 2018 through FY 2020 to determine Factor 2 for FY 2021.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38197 and 38198), we explained that we determined the source that, on balance, best meets all of these considerations is the uninsured estimates produced by CMS' Office of the Actuary (OACT) as part of the development of the National Health Expenditure Accounts (NHEA). The NHEA represents the government's official estimates of economic activity (spending) within the health sector. The information contained in the NHEA has been used to study numerous topics related to the health care sector, including, but not limited to, changes in the amount and cost of health services purchased and the payers or programs that provide or purchase these services; the economic causal factors at work in the health sector; the impact of policy changes, including major health reform; and comparisons to other countries' health spending. Of relevance to the determination of Factor 2 is that the comprehensive and integrated structure of the NHEA creates an ideal tool for evaluating changes to the health care system, such as the mix of the insured and uninsured, because this information is integral to the well-established NHEA methodology. In this section of this proposed rule, we describe some aspects of the methodology used to develop the NHEA that were particularly relevant in estimating the percent change in the rate of uninsurance for FY 2018 through FY 2020 that we believe continue to be relevant in developing the estimate for FY 2021. A full description of the methodology used to develop the NHEA is available on the CMS website at: *https://www.cms.gov/files/document/definitions-sources-and-methods.pdf*.

The NHEA estimates of U.S. population reflect the Census Bureau's definition of the resident-based population, which includes all people who usually reside in the 50 States or the District of Columbia, but excludes residents living in Puerto Rico and areas under U.S. sovereignty, members of the U.S. Armed Forces overseas, and U.S. citizens whose usual place of residence is outside of the United States, plus a small (typically less than 0.2 percent of population) adjustment to reflect Census undercounts. In past years, the estimates for Factor 2 were made using the CBO's uninsured population estimates for the under 65 population. For FY 2018 and subsequent years, the statute does not restrict the estimate to the measurement of the percent of individuals under the age of 65 who are uninsured. Accordingly, as we explained in the FY 2018 IPPS/LTCH PPS proposed and final rules, we believe it is appropriate to use an estimate that reflects the rate of uninsurance in the United States across all age groups. In addition, we continue to believe that a resident-based population estimate more fully reflects the levels of uninsurance in the United States that influence uncompensated care for hospitals than an estimate that reflects only legal residents. The NHEA estimates of uninsurance are for the total U.S. population (all ages) and not by specific age cohort, such as the population under the age of 65.

The NHEA includes comprehensive enrollment estimates for total private health insurance (PHI) (including direct and employer-sponsored plans), Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and other public programs, and estimates of the number of individuals who are uninsured. Estimates of total PHI enrollment are available for 1960 through 2018, estimates of Medicaid, Medicare, and CHIP enrollment are available for the length of the respective programs, and all other estimates (including the more detailed estimates of direct-purchased and employer-sponsored insurance) are available for 1987 through 2018. The NHEA data are publicly available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html*.

In order to compute Factor 2, the first metric that is needed is the proportion of the total U.S. population that was uninsured in 2013. In developing the estimates for the NHEA, OACT's methodology included using the number of uninsured individuals for 1987 through 2009 based on the enhanced Current Population Survey (CPS) from the State Health Access Data Assistance Center (SHADAC). The CPS, sponsored jointly by the U.S. Census Bureau and the U.S. Bureau of Labor Statistics (BLS), is the primary source of labor force statistics for the population of the United States. (We refer readers to the website at: *http://www.census.gov/programs-surveys/cps.html*.) The enhanced CPS, available from SHADAC (available at: *http://datacenter.shadac.org*) accounts for changes in the CPS methodology over time. OACT further adjusts the enhanced CPS for an estimated undercount of Medicaid enrollees (a population that is often not fully captured in surveys that include Medicaid enrollees due to a perceived stigma associated with being enrolled in the Medicaid program or confusion about the source of their health insurance).

To estimate the number of uninsured individuals for 2010 through 2018, the OACT extrapolates from the 2009 CPS data using data from the National Health Interview Survey (NHIS). The NHIS is one of the major data collection programs of the National Center for Health Statistics (NCHS), which is part of the Centers for Disease Control and Prevention (CDC). The U.S. Census Bureau is the data collection agent for

the NHIS. The NHIS results have been instrumental over the years in providing data to track health status, health care access, and progress toward achieving national health objectives. For further information regarding the NHIS, we refer readers to the CDC website at: *https://www.cdc.gov/nchs/nhis/index.htm*.

The next metrics needed to compute Factor 2 are projections of the rate of uninsurance in both CY 2020 and CY 2021. On an annual basis, OACT projects enrollment and spending trends for the coming 10-year period. Those projections (currently for years 2019 through 2028) use the latest NHEA historical data, which presently run through 2018. The NHEA projection methodology accounts for expected changes in enrollment across all of the categories of insurance coverage previously listed. The sources for projected growth rates in enrollment for Medicare, Medicaid, and CHIP include the latest Medicare Trustees Report, the Medicaid Actuarial Report, or other updated estimates as produced by OACT. Projected rates of growth in enrollment for private health insurance and the uninsured are based largely on OACT's econometric models, which rely on the set of macroeconomic assumptions underlying the latest Medicare Trustees Report. Greater detail can be found in OACT's report titled ''Projections of National Health Expenditure: Methodology and Model Specification,'' which is available on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf*.

The use of data from the NHEA to estimate the rate of uninsurance is consistent with the statute and meets the criteria we have identified for determining the appropriate data source. Section 1886(r)(2)(B)(ii) of the Act instructs the Secretary to estimate the rate of uninsurance for purposes of Factor 2 based on data from the Census Bureau or other sources the Secretary determines appropriate. The NHEA utilizes data from the Census Bureau; the estimates are available in time for the IPPS rulemaking cycle; the estimates are produced by OACT on an annual basis and are expected to continue to be produced for the foreseeable future; and projections are available for calendar year time periods that span the upcoming fiscal year. Timeliness and continuity are important considerations because of our need to be able to update this estimate annually. Accuracy is also a very important consideration and, all things being equal, we would choose the most accurate data source that sufficiently meets our other criteria.

(2) Proposed Factor 2 for FY 2021

Using these data sources and the previously described methodologies, the OACT estimates that the uninsured rate for the historical, baseline year of 2013 was 14 percent and for CYs 2020 and 2021 is 9.5 percent and 9.5 percent, respectively.[462] As required by section 1886(r)(2)(B)(ii) of the Act, the Chief Actuary of CMS has certified these estimates.

As with the CBO estimates on which we based Factor 2 in prior fiscal years, the NHEA estimates are for a calendar year. In the rulemaking for FY 2014, many commenters noted that the uncompensated care payments are made for the fiscal year and not on a calendar year basis and requested that CMS normalize the CBO estimate to reflect a fiscal year basis. Specifically, commenters requested that CMS calculate a weighted average of the CBO estimate for October through December 2013 and the CBO estimate for January through September 2014 when determining Factor 2 for FY 2014. We agreed with the commenters that normalizing the estimate to cover FY 2014 rather than CY 2014 would more accurately reflect the rate of uninsurance that hospitals would experience during the FY 2014 payment year. Accordingly, we estimated the rate of uninsurance for FY 2014 by calculating a weighted average of the CBO estimates for CY 2013 and CY 2014 (78 FR 50633). We have continued this weighted average approach of rate of uninsurance projections for each Federal fiscal year since the FY 2014 IPPS/LTCH PPS final rule.

We continue to believe that, in order to estimate the rate of uninsurance during a fiscal year more accurately, Factor 2 should reflect the estimated rate of uninsurance that hospitals will experience during the fiscal year, rather than the rate of uninsurance during only one of the calendar years that the fiscal year spans. Accordingly, we are proposing to continue to apply the weighted average approach used in past fiscal years in order to estimate the rate of uninsurance for FY 2021. The OACT has certified this estimate of the fiscal year rate of uninsurance to be reasonable and appropriate for purposes of section 1886(r)(2)(B)(ii) of the Act. We may also consider the use of more recent data that may become available for purposes of estimating the rates of uninsurance used in the calculation of the final Factor 2 for FY 2021.

The calculation of the proposed Factor 2 for FY 2021 using a weighted average of the OACT's projections for CY 2020 and CY 2021 is as follows:

- Percent of individuals without insurance for CY 2013: 14 percent.
- Percent of individuals without insurance for CY 2020: 9.5 percent.
- Percent of individuals without insurance for CY 2021: 9.5 percent.
- Percent of individuals without insurance for FY 2021 (0.25 times 0.095) + (0.75 times 0.095): 9.5 percent.

$1-|((0.095-0.14)/0.14)| = 1-0.3214 = 0.6786$ (67.86 percent).

For FY 2020 and subsequent fiscal years, section 1886(r)(2)(B)(ii) of the Act no longer includes any reduction to the previous calculation. Therefore, we are proposing that Factor 2 for FY 2021 would be 67.86 percent.

The proposed FY 2021 uncompensated care amount is $\$15,358,534,714.46 \times 0.6786 = \$7,816,726,242.92$.

Proposed FY 2021 Uncompensated Care Amount	$7,816,726,242.92

We are inviting public commentson our proposed methodology for calculating Factor 2 for FY 2021.

c. Calculation of Proposed Factor 3 for FY 2021

(1) General Background

Section 1886(r)(2)(C) of the Act defines Factor 3 in the calculation of the uncompensated care payment. As we have discussed earlier, section 1886(r)(2)(C) of the Act states that Factor 3 is equal to the percent, for each subsection (d) hospital, that represents the quotient of: (1) The amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data (including, in the case where the Secretary determines alternative data are available that are a

[462] Certification of Rates of Uninsured. April 3, 2020. Available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInPatientPPS/dsh.html*.

better proxy for the costs of subsection (d) hospitals for treating the uninsured, the use of such alternative data)); and (2) the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period (as so estimated, based on such data).

Therefore, Factor 3 is a hospital-specific value that expresses the proportion of the estimated uncompensated care amount for each subsection (d) hospital and each subsection (d) Puerto Rico hospital with the potential to receive Medicare DSH payments relative to the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the fiscal year for which the uncompensated care payment is to be made. Factor 3 is applied to the product of Factor 1 and Factor 2 to determine the amount of the uncompensated care payment that each eligible hospital will receive for FY 2014 and subsequent fiscal years. In order to implement the statutory requirements for this factor of the uncompensated care payment formula, it was necessary to determine: (1) The definition of uncompensated care or, in other words, the specific items that are to be included in the numerator (that is, the estimated uncompensated care amount for an individual hospital) and the denominator (that is, the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the applicable fiscal year); (2) the data source(s) for the estimated uncompensated care amount; and (3) the timing and manner of computing the quotient for each hospital estimated to receive Medicare DSH payments. The statute instructs the Secretary to estimate the amounts of uncompensated care for a period based on appropriate data. In addition, we note that the statute permits the Secretary to use alternative data in the case where the Secretary determines that such alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured.

In the course of considering how to determine Factor 3 during the rulemaking process for FY 2014, the first year this provision was in effect, we considered defining the amount of uncompensated care for a hospital as the uncompensated care costs of that hospital and determined that Worksheet S–10 of the Medicare cost report potentially provides the most complete data regarding uncompensated care costs for Medicare hospitals. However, because of concerns regarding variations in the data reported on Worksheet S–10 and the completeness of these data, we did not use Worksheet S–10 data to determine Factor 3 for FY 2014, or for FYs 2015, 2016, or 2017. Instead, we believed that the utilization of insured low-income patients, as measured by patient days, would be a better proxy for the costs of hospitals in treating the uninsured and therefore appropriate to use in calculating Factor 3 for these years. Of particular importance in our decision making was the relative newness of Worksheet S–10, which went into effect on May 1, 2010. At the time of the rulemaking for FY 2014, the most recent available cost reports would have been from FYs 2010 and 2011, which were submitted on or after May 1, 2010, when the new Worksheet S–10 went into effect. We believed that concerns about the standardization and completeness of the Worksheet S–10 data could be more acute for data collected in the first year of the Worksheet's use (78 FR 50635). In addition, we believed that it would be most appropriate to use data elements that have been historically publicly available, subject to audit, and used for payment purposes (or that the public understands will be used for payment purposes) to determine the amount of uncompensated care for purposes of Factor 3 (78 FR 50635). At the time we issued the FY 2014 IPPS/LTCH PPS final rule, we did not believe that the available data regarding uncompensated care from Worksheet S–10 met these criteria and, therefore, we believed they were not reliable enough to use for determining FY 2014 uncompensated care payments. For FYs 2015, 2016, and 2017, the cost reports used for calculating uncompensated care payments (that is, FYs 2011, 2012, and 2013) were also submitted prior to the time that hospitals were on notice that Worksheet S–10 could be the data source for calculating uncompensated care payments. Therefore, we believed it was also appropriate to use proxy data to calculate Factor 3 for these years. We indicated our belief that Worksheet S–10 could ultimately serve as an appropriate source of more direct data regarding uncompensated care costs for purposes of determining Factor 3 once hospitals were submitting more accurate and consistent data through this reporting mechanism.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38202), we stated that we could no longer conclude that alternative data to the Worksheet S–10 are available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. Hospitals were on notice as of FY 2014 that Worksheet S–10 could eventually become the data source for CMS to calculate uncompensated care payments. Furthermore, hospitals' cost reports from FY 2014 had been publicly available for some time, and CMS had analyses of Worksheet S–10, conducted both internally and by stakeholders, demonstrating that Worksheet S–10 accuracy had improved over time. Analyses performed by MedPAC had already shown that the correlation between audited uncompensated care data from 2009 and the data from the FY 2011 Worksheet S–10 was over 0.80, as compared to a correlation of approximately 0.50 between the audited uncompensated care data and 2011 Medicare SSI and Medicaid days. Based on this analysis, MedPAC concluded that use of Worksheet S–10 data was already better than using Medicare SSI and Medicaid days as a proxy for uncompensated care costs, and that the data on Worksheet S–10 would improve over time as the data are actually used to make payments (81 FR 25090). In addition, a 2007 MedPAC analysis of data from the Government Accountability Office (GAO) and the American Hospital Association (AHA) had suggested that Medicaid days and low-income Medicare days are not an accurate proxy for uncompensated care costs (80 FR 49525).

Subsequent analyses from Dobson/DaVanzo, originally commissioned by CMS for the FY 2014 rulemaking and updated in later years, compared Worksheet S–10 and IRS Form 990 data and assessed the correlation in Factor 3s derived from each of the data sources. Our analyses on balance led us to believe that we had reached a tipping point in FY 2018 with respect to the use of the Worksheet S–10 data. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38201 through 38203) for a complete discussion of these analyses.

We found further evidence for this tipping point when we examined changes to the FY 2014 Worksheet S–10 data submitted by hospitals following the publication of the FY 2017 IPPS/LTCH PPS final rule. In the FY 2017 IPPS/LTCH PPS final rule, as part of our ongoing quality control and data improvement measures for the Worksheet S–10, we referred readers to Change Request 9648, Transmittal 1681, titled ''The Supplemental Security Income (SSI)/Medicare Beneficiary Data for Fiscal Year 2014 for Inpatient Prospective Payment System (IPPS) Hospitals, Inpatient Rehabilitation Facilities (IRFs), and Long Term Care

Hospitals (LTCHs),'' issued on July 15, 2016 (available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R1681OTN.pdf*). In this transmittal, as part of the process for ensuring complete submission of Worksheet S–10 by all eligible DSH hospitals, we instructed MACs to accept amended Worksheets S–10 for FY 2014 cost reports submitted by hospitals (or initial submissions of Worksheet S–10 if none had been submitted previously) and to upload them to the Health Care Provider Cost Report Information System (HCRIS) in a timely manner. The transmittal stated that, for revisions to be considered, hospitals were required to submit their amended FY 2014 cost report containing the revised Worksheet S–10 (or a completed Worksheet S–10 if no data were included on the previously submitted cost report) to the MAC no later than September 30, 2016. For the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19949 through 19950), we examined hospitals' FY 2014 cost reports to see if the Worksheet S–10 data on those cost reports had changed as a result of the opportunity for hospitals to submit revised Worksheet S–10 data for FY 2014. Specifically, we compared hospitals' FY 2014 Worksheet S–10 data as they existed in the first quarter of CY 2016 with data from the fourth quarter of CY 2016. We found that the FY 2014 Worksheet S–10 data had changed over that time period for approximately one quarter of hospitals that receive uncompensated care payments. The fact that the Worksheet S–10 data changed for such a significant number of hospitals following a review of the cost report data they originally submitted and that the revised Worksheet S–10 information is available to be used in determining uncompensated care costs contributed to our belief that we could no longer conclude that alternative data are available that are a better proxy than the Worksheet S–10 data for the costs of subsection (d) hospitals for treating individuals who are uninsured.

We also recognized commenters' concerns that, in using Medicaid days as part of the proxy for uncompensated care, it would be possible for hospitals in States that choose to expand Medicaid to receive higher uncompensated care payments because they may have more Medicaid patient days than hospitals in a State that does not choose to expand Medicaid. Because the earliest Medicaid expansions under the Affordable Care Act began in 2014, the 2011, 2012, and 2013 Medicaid days used to calculate uncompensated care payments in FYs 2015, 2016, and 2017 are the latest available data on Medicaid utilization that do not reflect the effects of these Medicaid expansions. Accordingly, if we had used only low-income insured days to estimate uncompensated care for FY 2018, we would have needed to hold the time period of these data constant and use data on Medicaid days from 2011, 2012, and 2013 in order to avoid the risk of any redistributive effects arising from the decision to expand Medicaid in certain States. As a result, we would have been using older data that may provide a less accurate proxy for the level of uncompensated care being furnished by hospitals, contributing to our growing concerns regarding the continued use of low-income insured days as a proxy for uncompensated care costs in FY 2018.

To address concerns raised by commenters regarding a lack of clear and concise line level instructions, CMS issued Transmittal 10, which clarified and revised the instructions for reporting charity care on Worksheet S–10. For a discussion of the revisions and clarifications included in Transmittal 10, we refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42360). On September 29, 2017, we issued Transmittal 11, which clarified the definitions and instructions for uncompensated care, non-Medicare bad debt, non-reimbursed Medicare bad debt, and charity care, as well as modifying the calculations relative to uncompensated care costs and adding edits to ensure the integrity of the data reported on Worksheet S–10. Transmittal 11 is available for download on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R11p240.pdf*. We further clarified that full or partial discounts given to uninsured patients who meet the hospital's charity care policy or financial assistance policy/uninsured discount policy (hereinafter referred to as Financial Assistance Policy or FAP) may be included on Line 20, Column 1 of Worksheet S–10. These clarifications applied to cost reporting periods beginning on or after October 1, 2013. We also modified the application of the CCR. We specified that the CCR will not be applied to the deductible and coinsurance amounts for insured patients approved for charity care and non-reimbursed Medicare bad debt. The CCR will be applied to the charges for uninsured patients approved for charity care or an uninsured discount, non-Medicare bad debt, and charges for noncovered days exceeding a length of stay limit imposed on patients covered by Medicaid or other indigent care programs. As discussed in more detail in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42360 and 42361), we have also provided opportunities for hospitals to submit revisions to their Worksheet S–10 data for FY 2014 and FY 2015 cost reports.

As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41424), due to the overwhelming feedback from commenters emphasizing the importance of audits in ensuring the accuracy and consistency of data reported on the Worksheet S–10, we expected to begin audits of the Worksheet S–10 in the Fall of 2018. The audit protocol instructions were still under development at the time of the FY 2019 IPPS/LTCH PPS final rule; yet, we noted the audit protocols would be provided to the MACs in advance of the audit. Once the audit protocol instructions were complete, we began auditing the Worksheet S–10 data for selected hospitals in the Fall of 2018 so that the audited uncompensated care data from these hospitals would be available in time for use in the FY 2020 IPPS/LTCH PPS proposed rule. The audits began with 1 year of data (that is, FY 2015 cost reports) in order to maximize the available audit resources and not spread those audit resources over multiple years, potentially diluting their effectiveness. We chose to begin the audits with the FY 2015 cost reports primarily because this was the most recent year of data that we had broadly allowed to be resubmitted by hospitals, and many hospitals had already made considerable efforts to amend their FY 2015 reports in preparation for the FY 2019 rulemaking. We also considered that we had used the FY 2015 data as part of the calculation of the FY 2019 uncompensated care payments; therefore, the data had been subject to public comment and scrutiny.

(2) Background on the Methodology Used To Calculate Factor 3 for FY 2020

Section 1886(r)(2)(C) of the Act governs both the selection of the data to be used in calculating Factor 3, and also allows the Secretary the discretion to determine the time periods from which we will derive the data to estimate the numerator and the denominator of the Factor 3 quotient. Specifically, section 1886(r)(2)(C)(i) of the Act defines the numerator of the quotient as the amount of uncompensated care for such hospital for a period selected by the Secretary. Section 1886(r)(2)(C)(ii) of the Act defines the denominator as the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a

payment under section 1886(r) of the Act for such period. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50638), we adopted a process of making interim payments with final cost report settlement for both the empirically justified Medicare DSH payments and the uncompensated care payments required by section 3133 of the Affordable Care Act. Consistent with that process, we also determined the time period from which to calculate the numerator and denominator of the Factor 3 quotient in a way that would be consistent with making interim and final payments. Specifically, we must have Factor 3 values available for hospitals that we estimate will qualify for Medicare DSH payments and for those hospitals that we do not estimate will qualify for Medicare DSH payments but that may ultimately qualify for Medicare DSH payments at the time of cost report settlement.

In the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19418 and 19419), we proposed to use audited FY 2015 data to calculate Factor 3 for FY 2020. Given that we had conducted audits of the FY 2015 Worksheet S–10 data and had previously used the FY 2015 data to determine uncompensated care payments, and the fact that the FY 2015 data were the most recent data that we had allowed to be resubmitted to date, we believed, on balance, that the FY 2015 Worksheet S–10 data were the best available data to use for calculating Factor 3 for FY 2020.

In the FY 2020 IPPS/LTCH PPS proposed rule, we recognized that, for FY 2019, we used 3 years of data in the calculation of Factor 3 in order to smooth over anomalies between cost reporting periods and to mitigate undue fluctuations in the amount of uncompensated care payments from year to year. However, we stated that, for FY 2020, we believed mixing audited and unaudited data for individual hospitals by averaging multiple years of data could potentially lead to a less smooth result, which would be counter to our original goal in using 3 years of data. As we stated in the FY 2020 IPPS/LTCH PPS proposed rule, to the extent that the audited FY 2015 data for a hospital are relatively different from its unaudited FY 2014 data and/or its unaudited FY 2016 data, we potentially would be diluting the effect of our considerable auditing efforts and introducing unnecessary variability into the calculation if we continued to use 3 years of data to calculate Factor 3. As an example, we noted that approximately 10 percent of audited hospitals had more than a $20 million difference between their audited FY 2015 data and their unaudited FY 2016 data.

Although we proposed to use the Worksheet S–10 data from the FY 2015 cost reports to calculate Factor 3 for FY 2020, we acknowledged that some hospitals had raised concerns regarding some of the adjustments made to the FY 2015 cost reports following the audits of those cost reports (for example adjustments made to Line 22 of Worksheet S–10). In particular, hospitals had raised concerns regarding the instructions in effect for FY 2015, especially compared to the reporting instructions that were effective for cost reporting periods beginning on or after October 1, 2016, contending that some adjustments would not have been made if CMS had chosen as an alternative to audit the FY 2017 reports. Accordingly, we sought public comments on whether the changes in the reporting instructions between the FY 2015 cost reports and the FY 2017 cost reports had resulted in a better common understanding among hospitals of how to report uncompensated care costs and improved relative consistency and accuracy across hospitals in reporting these costs. We also sought public comments on whether, due to the changes in the reporting instructions, we should use a single year of uncompensated care cost data from the FY 2017 reports, instead of the FY 2015 reports, to calculate Factor 3 for FY 2020.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42368), we finalized our proposal to use the FY 2015 Worksheet S–10 cost report data in the methodology for determining Factor 3 for FY 2020. Although some commenters expressed support for the alternative policy of using the FY 2017 Worksheet S–10 data to determine each hospital's share of uncompensated care costs in FY 2020, given the feedback from commenters in response to both the FY 2019 and FY 2020 IPPS/LTCH PPS proposed rules, emphasizing the importance of audits in ensuring the accuracy and consistency of data reported on the Worksheet S–10, we concluded that the FY 2015 Worksheet S–10 data were the best available audited data to be used in determining Factor 3 for FY 2020. We also noted that we had begun auditing the FY 2017 data in July 2019, with the goal of having the FY 2017 audited data available for future rulemaking.

With respect to the Worksheet S–10 data, we indicated our belief that the definition of uncompensated care adopted in FY 2018 was still appropriate because it incorporates the most commonly used factors within uncompensated care as reported by stakeholders, including charity care costs and non-Medicare bad debt costs. Therefore, for purposes of calculating Factor 3 and uncompensated care costs for FY 2020, we again defined ''uncompensated care'' as the amount on Line 30 of Worksheet S–10, which is the cost of charity care (Line 23) and the cost of non-Medicare bad debt and non-reimbursable Medicare bad debt (Line 29).

In the FY 2020 IPPS/LTCH PPS final rule, we continued to apply the following policies as part of the Factor 3 methodology: (1) The merger policies that were initially adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50020); (2) the policy for providers with multiple cost reports, beginning in the same fiscal year, of using the longest cost report and annualizing Medicaid data and uncompensated care data if a hospital's cost report does not equal 12 months of data; (3) the policy for the rare cases where a provider has multiple cost reports, beginning in the same fiscal year, but one report also spans the entirety of the following fiscal year, such that the hospital has no cost report for that fiscal year, of using the cost report that spans both fiscal years for the latter fiscal year; and (4) the policies regarding the application of statistical trim methodologies to potentially aberrant CCRs and potentially aberrant uncompensated care costs reported on the Worksheet S–10.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 19419), we finalized a modified new hospital policy for new hospitals that did not have data for the cost reporting period(s) used in the Factor 3 calculation for FY 2020. Generally, new hospitals do not yet have available data to project their eligibility for DSH payments because there is a lag until the SSI ratio and Medicaid ratio become available. However, we noted that there are some hospitals (that is, hospitals with CCNs established after October 1, 2015) that have a preliminary projection of being eligible for DSH payments based on their most recent available disproportionate patient percentages. Under the modified policy adopted for FY 2020, new hospitals that are eligible for Medicare DSH may receive interim empirically justified DSH payments. However, because these hospitals do not have a FY 2015 cost report to use in the Factor 3 calculation and the projection of eligibility for DSH payments is still preliminary, the MAC will make a final determination concerning whether the hospital is eligible to receive Medicare DSH payments at cost report settlement based on its FY 2020 cost report. If the

hospital is ultimately determined to be eligible for Medicare DSH payments for FY 2020, the hospital will receive an uncompensated care payment calculated using a Factor 3, where the numerator is the uncompensated care costs reported on Worksheet S–10 of the hospital's FY 2020 cost report, and the denominator is the sum of the uncompensated care costs reported on Worksheet S–10 of the FY 2015 cost reports for all DSH-eligible hospitals. In the FY 2020 IPPS/LTCH PPS final rule, we noted that, given the time period of the data used to calculate Factor 3, any hospitals with a CCN established after October 1, 2015, would be considered new and subject to this policy in FY 2020.

For a discussion of the policy that we finalized for FY 2020 for new Puerto Rico hospitals, we refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42370 and 42371). In brief, Puerto Rico hospitals that do not have a FY 2013 cost report are considered new hospitals and subject to the new hospital policy, as previously discussed. Specifically, the numerator of the Factor 3 calculation will be the uncompensated care costs reported on Worksheet S–10 of the hospital's FY 2020 cost report and the denominator is the same denominator that is determined prospectively for purposes of determining Factor 3 for all DSH-eligible hospitals. We stated that we believe the discussion in the FY 2020 IPPS/LTCH PPS proposed rule of our intent to determine Factor 3 for these hospitals using their uncompensated care costs gave new Puerto Rico hospitals sufficient time to take the steps necessary to ensure that their uncompensated care costs for FY 2020 are accurately reported on their FY 2020 Worksheet S–10. In addition, we indicated that we expect MACs to review FY 2020 reports from new hospitals, as necessary, which will address past commenters' concerns regarding the need for further review of Puerto Rico hospitals' uncompensated care data before these data are used to determine Factor 3.

In the FY 2020 IPPS/LTCH PPS final rule (83 FR 42371), for Indian Health Service and Tribal hospitals, and subsection (d) Puerto Rico hospitals that have a FY 2013 cost report, we continued the policy we first adopted for FY 2018 of substituting data regarding FY 2013 low-income insured days for the Worksheet S–10 data when determining Factor 3. As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38209), the use of data from Worksheet S–10 to calculate the uncompensated care amount for Indian Health Service and Tribal hospitals may jeopardize these hospitals' uncompensated care payments due to their unique funding structure. With respect to Puerto Rico hospitals that would not be subject to the new hospital policy, we indicated that we continued to agree with concerns raised by commenters that the uncompensated care data reported by these hospitals need to be further examined before the data are used to determine Factor 3. Accordingly, for these hospitals, we determined Factor 3 based on Medicaid days from FY 2013 and the most recent update of SSI days. The aggregated amount of uncompensated care that is used in the Factor 3 denominator for these hospitals continued to be based on the low-income patient proxy; that is, the aggregate amount of uncompensated care determined for all DSH-eligible hospitals using the low-income insured days proxy. We stated our belief that this approach was appropriate as the FY 2013 data reflect the most recent available information regarding these hospitals' low-income insured days before any expansion of Medicaid. In addition, because we continued to use 1 year of insured low-income patient days as a proxy for uncompensated care for Puerto Rico hospitals and residents of Puerto Rico are not eligible for SSI benefits, we continued to use a proxy for SSI days for Puerto Rico hospitals consisting of 14 percent of the hospital's Medicaid days, as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56953 through 56956).

Therefore, for FY 2020, we computed Factor 3 for each hospital by—

Step 1: Selecting the provider's longest cost report from its Federal fiscal year (FFY) 2015 cost reports. (Alternatively, in the rare case when the provider has no FFY 2015 cost report because the cost report for the previous Federal fiscal year spanned the FFY 2015 time period, the previous Federal fiscal year cost report would be used in this step.)

Step 2: Annualizing the uncompensated care costs (UCC) from Worksheet S–10 Line 30, if the cost report is more than or less than 12 months. (If applicable, use the statewide average CCR (urban or rural) to calculate uncompensated care costs.)

Step 3: Combining annualized uncompensated care costs for hospitals that merged.

Step 4: Calculating Factor 3 for Indian Health Service and Tribal hospitals and Puerto Rico hospitals that have a FY 2013 cost report using the low-income insured days proxy based on FY 2013 cost report data and the most recent available SSI ratio (or, for Puerto Rico hospitals, 14 percent of the hospital's FY 2013 Medicaid days). (Alternatively, in the rare case when the provider has no FFY applicable cost report because the cost report for the previous Federal fiscal year spanned the time period, the previous Federal fiscal year cost report would be used in this step.) The denominator is calculated using the low-income insured days proxy data from all DSH eligible hospitals. Consistent with the policy adopted in the FY 2019 IPPS/LTCH PPS final rule, if a hospital did not have both Medicaid days for FY 2013 and SSI days for FY 2017 available for use in the calculation of Factor 3 in Step 4, we considered the hospital not to have data available for Step 4.

Step 5: Calculating Factor 3 for the remaining DSH eligible hospitals using annualized uncompensated care costs (Worksheet S–10 Line 30) based on FY 2015 cost report data (from Step 3). The hospitals for which Factor 3 was calculated in Step 4 are excluded from this calculation.

We amended the regulations at § 412.106 by adding a new paragraph (g)(1)(iii)(C)(*6*) to reflect the methodology for computing Factor 3 for FY 2020.

(3) Proposed Methodology for Calculating Factor 3 for FY 2021 and Subsequent Fiscal Years

(a) Proposal To Use Audited FY 2017 Data To Calculate Factor 3 for FY 2021

Since the publication of the FY 2020 IPPS/LTCH PPS final rule, we have continued to monitor the reporting of Worksheet S–10 data in order to determine the most appropriate data to use in the calculation of Factor 3 for FY 2021. Audits of FY 2017 cost reports began in June 2019 and those audited reports are now available, in time for the development of this proposed rule. Feedback from the audits of the FY 2015 reports and lessons learned were incorporated into the audit process for the FY 2017 reports. We again chose to audit 1 year of data (that is, FY 2017) in order to maximize the available audit resources and not spread those audit resources over multiple years, potentially diluting their effectiveness.

Given that the FY 2017 Worksheet S–10 data were submitted under the revised cost reporting instructions that were effective on October 1, 2017, and we have also undertaken provider outreach regarding potentially aberrant data in FY 2017 reports and conducted audits of these data (84 FR 42371), we believe, on balance, that the FY 2017 Worksheet S–10 data are the best available data to use for calculating

Factor 3 for FY 2021. For a detailed discussion of the cost reporting instruction changes between FY 2015 and FY 2017 reports, we refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42368 and 42369). For the reasons discussed in the FY 2020 IPPS/LTCH PPS proposed and final rules (84 FR 19419 and 84 FR 42364), we continue to believe that mixing audited and unaudited data for individual hospitals by averaging multiple years of data could potentially lead to a less smooth result. To the extent that the audited FY 2017 data for a hospital are relatively different from its FY 2015 data (whether audited or unaudited) and/or its unaudited FY 2016 data, we potentially would be diluting the effect of the revisions to the cost reporting instructions and our considerable auditing efforts, while introducing unnecessary variability into the calculation if we were to use multiple years of data to calculate Factor 3 for FY 2021. We recognize that the FY 2015 reports include audited data for some hospitals, however, the FY 2017 cost reports are the most recent year of audited data and, as previously discussed reflect the revisions to the Worksheet S–10 cost report instructions that were effective on October 1, 2017.

Accordingly, we are proposing to use a single year of Worksheet S–10 data from FY 2017 cost reports to calculate Factor 3 in the FY 2021 methodology for all eligible hospitals with the exception of Indian Health Service (IHS) and Tribal hospitals and Puerto Rico hospitals. As discussed in a later section, we are proposing to continue to use the low-income insured days proxy to calculate Factor 3 for these hospitals for one more year. We note that the proposed uncompensated care payments to hospitals whose FY 2017 Worksheet S–10 data have been audited represent approximately 65 percent of the proposed total uncompensated care payments for FY 2021. For purposes of this FY 2021 proposed rule, we have used a HCRIS extract updated through February 19, 2020. We note that we intend to use the March 2020 update of HCRIS for the FY 2021 final rule and the respective March updates for all future final rules. However, we invite the public to submit comments on this intention regarding the use of the March update of HCRIS, and we may also consider the use of more recent data that may become available after March 2020, but prior to the development of the final rule, if appropriate, for purposes of calculating the final Factor 3 for purposes of the FY 2021 IPPS/LTCH PPS final rule.

(b) Proposal To Use Most Recent Available Single Year of Audited Worksheet S–10 Data To Calculate Factor 3 for All Subsequent Fiscal Years

While the number of audited hospitals may change from year to year depending on audit experience and the availability of audit resources, we expect the Worksheet S–10 data for an increasing number of hospitals will be audited in future cost reporting years. As a result, we have confidence that the best available data in future years will be the Worksheet S–10 data for cost reporting years for which audits have been conducted. In addition, we believe that establishing a policy that would apply not only for FY 2021, but also for all subsequent fiscal years would help providers have greater predictability for planning purposes. Therefore, we are proposing that for FY 2022 and all subsequent fiscal years, we would use the most recent single year of cost report data that have been audited for a significant number of hospitals receiving substantial Medicare uncompensated care payments to calculate Factor 3 for all eligible hospitals, with the exception of Indian Health Service and Tribal hospitals. We note that we intend to consider the comments received on this proposed rule, and may revisit this proposal for FY 2022 and subsequent fiscal years either in the final rule or through future rulemaking.

Given the unique nature of IHS and Tribal Hospitals and of the patient populations they serve, we believe it may be appropriate to restructure Medicare DSH payments and uncompensated care payments to these hospitals beginning in FY 2022. As discussed in prior rulemaking (for example, 82 FR 38188), the principal mission of the IHS is the provision of health care to American Indians and Alaska Natives throughout the United States. In carrying out that mission, IHS operates under two primary authorizing statutes. The first statute, the Snyder Act, authorizes IHS to expend such moneys as Congress may determine from time to time appropriate for the conservation of the health of American Indians or Alaska Natives. We refer readers to 25 U.S.C. 13 (providing that the Bureau of Indian Affairs (BIA) will expend funds as appropriated for, among other things, the conservation of health of American Indians and Alaska Natives); and 42 U.S.C. 2001(a) (transferring the responsibility for American Indian and Alaska Native health care from BIA to HHS). The second statute, the Indian Health Care Improvement Act (IHCIA), established IHS as an agency within the Public Health Service of HHS and provides authority for numerous programs to address particular health initiatives for American Indians and Alaska Natives, such as alcohol and substance abuse and diabetes (25 U.S.C. 1601 *et seq.*). IHS and Tribal hospitals are charged with addressing the health of American Indians and Alaska Natives and are uniquely situated to provide services to this population.

When Congress was considering reductions to the Medicare DSH payments and the creation of the Medicare uncompensated care payments under section 3133 the Affordable Care Act, one significant source of available information was the analysis done by the Medicare Payment Advisory Commission (MedPAC) in its March 2007 Report to the Congress. We note that section 1886(r)(1) of the Act explicitly refers to this March 2007 Report to Congress as the basis for reducing DSH payments to 25 percent of the amount that would otherwise be paid under section 1886(d)(5)(F) of the Act. We have reviewed MedPAC's analysis in the March 2007 Report to Congress and it is not apparent that MedPAC was focused on the unique aspects of IHS and Tribal hospitals described above when developing its recommendations for possible changes to DSH payments. Rather, it appears that MedPAC's analysis was focused on broader underlying issues and hospitals more generally.

Given the unique nature of IHS and Tribal hospitals, and the fact that we do not believe that the DSH analysis available to Congress at the time section 3133 of the Affordable Care Act was being developed was focused on the specific circumstances of these hospitals, we believe it may be appropriate, beginning in FY 2022, to use our authority under section 1886(d)(5)(I)(i) of the Act to create an exception for IHS and Tribal hospitals from Medicare DSH payments under 1886(d)(5)(F), as amended by section 3133 of the Affordable Care Act. This exception would also have the consequence that IHS and Tribal hospitals would be excluded from the calculation of Medicare uncompensated care payments under 1886(r). Concurrently, we believe it may be appropriate to use our authority under section 1886(d)(5)(I)(i) to adjust payments to IHS and Tribal hospitals through the creation of a new IHS and Tribal hospital Medicare DSH payment. The methodology for determining this IHS and Tribal hospital Medicare DSH payment would mirror the calculation of the Medicare DSH payment under

1886(d)(5)(F) except that the payment would be determined at 100 percent of the calculated amount rather than 25 percent of the calculated amount as required under section 3133 of the Affordable Care Act. We seek comment on this potential restructuring of the Medicare DSH and uncompensated care payments to IHS and Tribal hospitals beginning in FY 2022. We also intend to consider input received on this issue through consultation with IHS and Tribal hospitals.

(c) Proposed Definition of ''Uncompensated Care''

We continue to believe that the definition of ''uncompensated care'' first adopted in FY 2018 when we started to incorporate data from Worksheet S–10 into the determination of Factor 3 and that was used again in both FY 2019 and FY 2020 is appropriate, as it incorporates the most commonly used factors within uncompensated care as reported by stakeholders, namely, charity care costs and bad debt costs, and correlates to Line 30 of Worksheet S–10. Therefore, we are proposing that, for purposes of determining uncompensated care costs and calculating Factor 3 for FY 2021 and subsequent fiscal years, ''uncompensated care'' would continue to be defined as the amount on Line 30 of Worksheet S–10, which is the cost of charity care (Line 23) and the cost of non-Medicare bad debt and non-reimbursable Medicare bad debt (Line 29). We refer readers to the FY 2020 IPPS/LTCH PPS rule (84 FR 42369 and 42370), for a detailed discussion of additional topics related to definition of uncompensated care.

In the FY 2020 IPPS/LTCH PPS final rule, we stated that, we would attempt to address commenters' concerns regarding the Worksheet S–10 through future cost report clarifications to further improve and refine the information that is reported on Worksheet S–10 in order to support collection of the information necessary to implement section 1886(r)(2) of the Act. (84 FR 42370). We note that the Paper Reduction Act (PRA) package for Form CMS–2552–10 (OMB Control Number 0938–0050, expiration date March 31, 2022) offers an additional opportunity to comment on the cost reporting instructions. For further information regarding PRA, we refer the reader to the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995*.

(d) Proposed Changes to the Methodology for Calculating Factor 3 for FY 2021 and Subsequent Fiscal Years

The proposed changes to the methodology for calculating Factor 3 include the following:

• Merger Multiplier for Acquired Hospital Data

In the FY 2015 IPPS/LTCH PPS final rule, we defined a merger as an acquisition where the Medicare provider agreement of one hospital is subsumed into the provider agreement of the surviving provider (79 FR 50020). In that final rule, we adopted a policy for calculating Factor 3 for hospitals that undergo a merger during or after the time period of the data that is used in the Factor 3 calculations, as well as a separate policy for a merger that occurs after the development of the final rule for the applicable fiscal year. A proposed policy for newly merged hospitals is discussed in the next section. In the FY 2019 IPPS/LTCH PPS final rule, we finalized a policy for determining the uncompensated care costs of hospitals that have multiple cost reporting periods starting in the same fiscal year of using the longest cost report beginning in the applicable fiscal year and annualizing the uncompensated care data if a hospital's cost report does not equal 12 months of data (83 FR 41427). This policy applied for all hospitals, including those involved in a merger. However, taking into consideration past comments regarding mergers, including comments on the FY 2019 IPPS/LTCH PPS proposed rule which suggested that we not annualize the uncompensated care costs data provided in short cost reporting periods for acquired hospitals because their uncompensated care costs for the remaining part of year are included in the new combined hospital's cost report (83 FR 41427), we are proposing to modify the annualization policy that was finalized in FY 2019 with respect to merged hospitals.

We note that for most mergers, the effective date of the merger coincides with the cost reporting end date for the hospital that is being acquired. In effect, this means that the FY 2015 merger policy of combining uncompensated care costs (UCC) across CCNs results in adding together data reported on the cost report for two different CCNs (the acquired hospital and the surviving hospital) to estimate the merged hospital's post-merger total UCC. For mergers with a recent merger effective date, such as a merger in Federal fiscal year 2019 (that is, a merger after the period of the FY 2017 cost reports we are proposing to use for the Factor 3 calculation), we continue to believe the current policy of annualizing and combining across historical cost reports produces the best available estimate for post-merger total UCC. For example, if the acquired hospital's FY 2017 cost report includes less than 12 months of data, we would annualize the data to reflect a full 12 months of data. Similarly, in this example, if the surviving hospital's cost report includes less than 12 months of data, we would annualize its uncompensated care data. However, as discussed below, we are proposing a modification to this policy when the merger effective date occurs partway through the surviving hospital's cost reporting period.

In some mergers, the merger effective date does not coincide with the start date for the surviving hospital's cost reporting period. When the merger effective date does not coincide with the start date of the surviving hospital's cost reporting period, the policy of annualizing the acquired hospital's data before combining data across hospital cost reports could substantially overestimate the acquired hospital's UCC, given that the surviving hospital's cost report reflects the UCC incurred by the acquired hospital during the portion of the year after the merger effective date. In other words, when the merger effective date is partway through the surviving hospital's cost reporting period, annualizing acquired hospital's data may double-count UCC for the portion of the year that overlaps with the remainder of the surviving hospital's cost reporting period.

Accordingly, when the merger effective date occurs partway through the surviving hospital's cost reporting period, to more accurately estimate UCC for the hospitals involved in a merger, we are proposing not to annualize the acquired hospital's data. Further, we are proposing to use only the portion of the acquired hospital's unannualized UCC data that reflects the UCC incurred prior to the merger effective date, but after the start of the surviving hospital's current cost reporting period. Specifically, we are proposing to calculate a multiplier to be applied to an acquired hospital's UCC when the merger effective date occurs partway through the surviving hospital's cost reporting period. This multiplier will represent the portion of the UCC data from the acquired hospital that should be incorporated with the surviving hospital's data to determine UCC for purposes of determining Factor 3 for the surviving hospital. This multiplier is obtained by calculating the number of days between the start of the

applicable cost reporting period for the surviving hospital and the merger effective date, and then dividing this result by the total number of days in the reporting period of the acquired hospital. Applying this multiplier to the acquired hospital's unannualized UCC data will determine the final portion of the acquired hospital's UCC that should be added to that of the surviving hospital for purposes of determining Factor 3.

As an example, if the cost reporting period start dates of the acquired and surviving hospitals align and a merger occurs halfway through the surviving hospital's cost reporting period (for example, the hospital's fiscal year), then ultimately, the cost report for the surviving hospital for that fiscal year would already reflect half a year of the acquired hospital's UCC (because the merger occurred halfway through the surviving hospital's cost reporting period and the UCC data reported by the surviving hospital incorporate any UCC incurred by the acquired hospital during the second half of the fiscal year). For illustrative purposes, consider that the cost reporting period start dates of the acquired and surviving hospitals are 10/01/2016; the cost reporting period end date of the acquired hospital is 06/30/2017; and the merger acquisition date is 07/01/2017. Thus, there are 273 days between the start of the cost reporting period of the surviving hospital and the merger effective date, and the cost reporting period of the acquired hospital is 273 days. The multiplier, as previously defined, would be 1 (273 days divided by 273 days) and all of the acquired hospital's unannualized UCC data for the period 10/01/2016 to 06/30/2017 would be added to that of the surviving hospital for purposes of calculating Factor 3 for FY 2021. It is not necessary to annualize the acquired hospital's data from its short cost report, because the UCC incurred by the acquired hospital for the remainder of the surviving hospital's fiscal year post-merger (07/01/2017 to 09/30/2017) are already included in the UCC data reported by the surviving hospital for the cost reporting period ending on 09/30/2017.

As another example, assume the merger effective date is the same as the start date for the surviving hospital's cost reporting period and the surviving hospital's cost reporting period is 12 months long. In this example, we believe it would not be necessary to combine uncompensated care costs across multiple cost reports, because the surviving hospital's cost report already reflects 12 months of uncompensated care costs for the merged hospital. In this example, the multiplier would be 0 because there are 0 days between the start of the surviving hospital's cost reporting period and the merger effective date, and there would be no need to combine data from the acquired hospital given that the surviving hospital's cost report reflects all post-merger UCC data for the acquired hospital.

- Newly Merged Hospitals

We propose to continue to treat hospitals that merge after the development of the final rule similar to new hospitals. As explained in the FY 2015 IPPS/LTCH PPS final rule, for these newly merged hospitals, we do not have data currently available to calculate a Factor 3 amount that accounts for the merged hospital's uncompensated care burden (79 FR 50021). In the FY 2015 IPPS/LTCH PPS final rule, we finalized a policy under which Factor 3 for hospitals that we do not identify as undergoing a merger until after the public comment period and additional review period following the publication of the final rule or that undergo a merger during the fiscal year would be recalculated similar to new hospitals (79 FR 50021 and 50022).

Consistent with the policy adopted in the FY 2015 IPPS/LTCH PPS final rule, we are proposing to treat newly merged hospitals in a similar manner as new hospitals, such that the newly merged hospital's final uncompensated care payment would be determined at cost report settlement where the numerator of the newly merged hospital's Factor 3 would be based on the cost report of only the surviving hospital (that is, the newly merged hospital's cost report) for the current fiscal year. However, if the hospital's cost reporting period includes less than 12 months of data, we propose that the newly merged hospital's cost report's data would be annualized for purposes of the Factor 3 calculation. We note that we are not proposing that the multiplier calculation discussed previously would be used, as that would only be necessary for estimating post-merger data using historical reports. The acquired hospital's uncompensated care payment for the fiscal year during which the merger occurs would be determined using the prospectively determined Factor 3 amount for the acquired hospital and then pro rated, if applicable. We refer the reader to the detailed discussion in the FY 2015 IPPS/LTCH PPS rule regarding the calculation of pro rata uncompensated care payments (79 FR 50151 through 50153).

Consistent with past policy, we also are proposing that the interim uncompensated care payments for the newly merged hospital would be based only on the data for the surviving hospital's CCN available the time of the development of the final rule. In other words, for FY 2021, eligibility for a newly merged hospital to receive interim uncompensated care payments and the amount of any interim uncompensated care payments, would be based only on the FY 2017 cost report available for the surviving CCN at the time the final rule is developed. However, at cost report settlement, we would determine the newly merged hospital's final uncompensated care payment based on the uncompensated care costs reported on its FY 2021 cost report. That is, we would revise the numerator of Factor 3 for the newly merged hospital to reflect the uncompensated care costs reported on the newly merged hospital's FY 2021 cost report.

- Annualization and Long Cost Reports

We are proposing to continue the policy that was finalized in the FY 2018 IPPS/LTCH PPS final rule of annualizing uncompensated care cost data reported on the Worksheet S–10 if a hospital's cost report does not equal 12 months of data, except in the case of mergers, which would be subject to the proposed modified merger policy previously discussed. In addition, we are proposing to continue the policies that were finalized in the FY 2019 IPPS/LTCH final rule (83 FR 41415) regarding the use of the longest cost report available within the Federal fiscal year. However, we are proposing to modify our current policy for those rare situations where a hospital has a cost report that starts in one fiscal year but spans the entirety of the following fiscal year such that the hospital has no cost report starting in that subsequent fiscal year. Under this proposal, we would use the cost report that spans both fiscal years for purposes of calculating Factor 3 when data for the latter fiscal year is used in the Factor 3 methodology. The current policy for this rare situation includes the criterion that the hospital have multiple cost reports beginning in the same fiscal year. However, we no longer believe this is a necessary condition, given that we have identified some hospitals that have no FY 2017 cost report, but that only have one FY 2016 cost report, which spans the entire FY 2017 period.

- New Hospital for Purposes of Factor 3

We are proposing to continue the new hospital policy that was finalized in the FY 2020 IPPS/LTCH PPS final rule.

Specifically, for new hospitals that do not have an FY 2017 cost report to use in the Factor 3 calculation (that is, hospitals with CCNs established on or after October 1, 2017) that may have a preliminary projection of being eligible for DSH payments based on their most recent available disproportionate patient percentage, we are proposing that the MAC would make a final determination concerning whether the hospital is eligible to receive Medicare DSH payments at cost report settlement based on its FY 2021 cost report. If the hospital is ultimately determined to be eligible for Medicare DSH payments for FY 2021, the hospital would receive an uncompensated care payment calculated using a Factor 3, where the numerator is the uncompensated care costs reported on Worksheet S–10 of the hospital's FY 2021 cost report, and the denominator is the sum of the uncompensated care costs reported on Worksheet S–10 of the FY 2017 cost reports for all DSH-eligible hospitals. This denominator would be the same denominator that is determined prospectively for purposes of determining Factor 3 for all DSH-eligible hospitals, with the exception of Puerto Rico hospitals and IHS and Tribal hospitals. The new hospital would not receive interim uncompensated care payments before cost report settlement because we would have no FY 2017 uncompensated care data on which to determine what those interim payments should be.

- IHS and Tribal Hospitals

For the reasons discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38209), we continue to recognize that the use of data from Worksheet S–10 to calculate the uncompensated care amount for IHS and Tribal hospitals for FY 2021 may jeopardize these hospitals' payments due to their unique funding structure. Prior to this proposed rulemaking for FY 2021, CMS consulted with IHS and Tribal hospitals regarding Worksheet S–10 uncompensated care reporting as well as any potential barriers under the current cost reporting instructions to reporting by IHS and Tribal hospitals on Worksheet S–10. During the consultation, representatives of some hospitals indicated that it was not clear to them that they could submit Worksheet S–10 data given the historical use of the low-income patient proxy when determining Factor 3 for these hospitals. CMS reiterated that the use of low-income patient proxy when determining Factor 3 does not preclude the submission of Worksheet S–10 data by these hospitals. CMS explained that IHS and Tribal Hospitals should be aware of and comply with the instructions and requirements for the submission of Worksheet S–10 data. For an overview of the instructions and requirements, one source is the MLN Matters® Special Edition article ''Updates to Medicare's Cost Report Worksheet S–10 to Capture Uncompensated Care Data'' that was released on September 29, 2017 and is available on the CMS website at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE17031.pdf*. Another source of information is the ''Worksheet S–10—Hospital Uncompensated and Indigent Care Data Following 2018 IPPS Final Rule Questions and Answers'' that is also available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/Worksheet-S-10-UCC-QandAs.pdf*. As discussed previously in this section, CMS continues to consider the feedback provided during IHS and Tribal consultation for purposes of determining what policies should apply with respect to DSH and uncompensated care payments to IHS and Tribal hospitals in future years. We also seek comment on this issue to assist future rulemaking. We also note that the Paper Reduction Act (PRA) package for Form CMS 2552–10 will be an additional opportunity for comments on the Worksheet S–10 instructions.

Therefore, for IHS and Tribal hospitals that have a FY 2013 cost report, we are proposing to continue the policy first adopted for the FY 2018 rulemaking regarding the low-income patient proxy. Specifically, for FY 2021 we are proposing to determine Factor 3 for these hospitals based on Medicaid days for FY 2013 and the most recent update of SSI days. The aggregate amount of uncompensated care that is used in the Factor 3 denominator for these hospitals would continue to be based on the low-income patient proxy; that is, the aggregate amount of uncompensated care determined for all DSH eligible hospitals using the low-income insured days proxy. We continue to believe this approach is appropriate because the FY 2013 data reflect the most recent available information regarding these hospitals' Medicaid days before any expansion of Medicaid. At the time of development of this proposed rule, for modeling purposes, we computed Factor 3 for these hospitals using FY 2013 Medicaid days from a HCRIS extract updated through February 19, 2020, and the most recent available FY 2018 SSI days.

- Puerto Rico Hospitals

With respect to Puerto Rico hospitals, we considered calculating their Factor 3 amounts for FY 2021 using the same methodology we are proposing for hospitals other than IHS and Tribal hospitals. However, we concluded that the recent natural disasters in Puerto Rico may negatively impact the ability of these hospitals to engage in the FY 2021 rulemaking on the particular issue of the data to be used to determine Factor 3 for Puerto Rico hospitals, while simultaneously focusing on ensuring that their FY 2018 uncompensated care Worksheet S–10 data is accurately reported and available for use in calculating FY 2022 Medicare uncompensated care payments consistent with our proposed approach for FY 2022 and subsequent fiscal years.

Accordingly, for FY 2021 we are proposing to determine Factor 3 for Puerto Rico hospitals that have a FY 2013 cost report based on the low-income patient proxy. We would determine Factor 3 for these hospitals based on Medicaid days for FY 2013 and the most recent update of SSI days. The aggregate amount of uncompensated care that is used in the Factor 3 denominator for these hospitals would continue to be based on the low-income patient proxy; that is, the aggregate amount of uncompensated care determined for all DSH eligible hospitals using the low-income insured days proxy. We continue to believe the use of FY 2013 data in determining the low-income insured days proxy is appropriate because the FY 2013 data reflect the most recent available information regarding these hospitals' Medicaid days before any expansion of Medicaid. At the time of development of the proposed rule, for modeling purposes, we computed Factor 3 for these hospitals using FY 2013 Medicaid days from a recent HCRIS extract and the most recent available FY 2018 SSI days. In addition, because we are proposing to continue to use 1 year of insured low-income patient days as a proxy for uncompensated care for Puerto Rico hospitals and residents of Puerto Rico are not eligible for SSI benefits, we are proposing to continue to use a proxy for SSI days for Puerto Rico hospitals, consisting of 14 percent *COM007*of a hospital's Medicaid days, as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56953 through 56956).

- All-Inclusive Rate Providers

In FY 2018 IPPS/LTCH PPS final rule (82 FR 38218), we indicated that we would further explore which trims are

appropriate to apply to the CCRs on Line 1 of Worksheet S–10, including whether it is appropriate to apply a unique trim to certain subsets of hospitals, such as all-inclusive rate providers. We noted that all-inclusive rate providers have the ability to compute and enter their appropriate CCR on Worksheet S–10, Line 1, by answering Yes to the question on Worksheet S–2, Part I, Line 115, and not have it computed using information from Worksheet C, Part I. We stated that we would give more consideration to the utilization of statewide averages in substituting outlier CCRs, and that we intended to consider other approaches that would ensure validity of the trim methodology and not penalize hospitals that use alternative methods of cost apportionment in future rulemaking. In the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19420), we stated that we had examined the CCRs from the FY 2015 cost reports and believed the risk that all-inclusive rate providers will have aberrant CCRs and, consequently, aberrant uncompensated care data, was mitigated by the proposal to apply the trim methodology for potentially aberrant uncompensated care costs to all hospitals.

In preparation for the FY 2021 rulemaking, we conducted a review of the CCRs from the FY 2017 cost reports from all-inclusive rate providers (AIRPs) and determined that in rare situations they may include a potentially aberrant CCR (Worksheet S–10 line 1) which results in a ratio of total UCC to total operating costs of greater than 50 percent. For FY 2021, we continue to believe that all-inclusive rate providers should be excluded from the CCR trim methodology because all-inclusive rate providers have alternative methods of cost apportionment that are different from those used in the standard CCR calculation. However, in order to ensure that we are able to calculate a reasonable estimate of the hospital's FY 2017 UCC, we are proposing to modify the potentially aberrant UCC trim methodology when it is applied to all-inclusive rate providers. Specifically, we are proposing that when an AIRP's total UCC are greater than 50 percent of its total operating costs when calculated using the CCR included on its FY 2017 cost report, we would recalculate UCC using the CCR reported on Worksheet S–10, line 1 of the hospital's most recent available prior year cost report that would not result in UCC of over 50 percent of total operating costs. That is, we would apply the CCR from Worksheet S–10 line 1 of that prior cost report to the data reported on Worksheet S–10 of the FY 2017 cost report. For purposes of this proposed rule, we identified a few AIRPs that have UCC in excess of 50 percent of their total operating costs. For these hospitals, we used the CCR from Worksheet S–10, line 1 of their FY 2015 cost report in place of the CCR reported on Worksheet S–10, line 1 of their FY 2017 cost report, in order to re-calculate their UCC. We believe this approach produces a more accurate estimate of the AIRP's UCC for purposes of determining Factor 3, while continuing to reflect the information on uncompensated care included in the AIRP's FY 2017 cost report, which for the reasons discussed previously we believe is the most appropriate data to be used in determining Factor 3 for FY 2021.

• Proposed CCR Trim Methodology

The calculation of a hospital's total uncompensated care costs on Worksheet S–10 requires the use of the hospital's cost to charge ratio (CCR). Similar to the process used in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38217 through 38218), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41415 and 41416), and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42372) for trimming CCRs, we are proposing the following steps to determine the applicable CCR:

Step 1: Remove Maryland hospitals. In addition, we would remove all-inclusive rate providers because their CCRs are not comparable to the CCRs calculated for other IPPS hospitals.

Step 2: For FY 2017 cost reports, calculate a CCR ''ceiling'' with the following data: for each IPPS hospital that was not removed in Step 1 (including non-DSH eligible hospitals), we would use cost report data to calculate a CCR by dividing the total costs on Worksheet C, Part I, Line 202, Column 3 by the charges reported on Worksheet C, Part I, Line 202, Column 8. (Combining data from multiple cost reports from the same fiscal year is not necessary, as the longer cost report would be selected.) The ceiling would be calculated as 3 standard deviations above the national geometric mean CCR for the applicable fiscal year. This approach is consistent with the methodology for calculating the CCR ceiling used for high-cost outliers. Remove all hospitals that exceed the ceiling so that these aberrant CCRs do not skew the calculation of the statewide average CCR. (For purposes of this proposed rule, this trim would remove 12 hospitals that have a CCR above the calculated ceiling of 0.937 for FY 2017 cost reports.)

Step 3: Using the CCRs for the remaining hospitals in Step 2, determine the urban and rural statewide average CCRs for FY 2017 for hospitals within each State (including non-DSH eligible hospitals), weighted by the sum of total hospital discharges from Worksheet S–3, Part I, Line 14, Column 15. (We note that this is not a change from the methodology used in past years. In past rules, we inadvertently referred to Column 14, rather than Column 15.)

Step 4: Assign the appropriate statewide average CCR (urban or rural) calculated in Step 3 to all hospitals, excluding all-inclusive rate providers, with a CCR for FY 2017 greater than 3 standard deviations above the national geometric mean for that fiscal year (that is, the CCR ''ceiling''). For this proposed rule, the statewide average CCR would apply to 12 hospitals, of which 4 hospitals have FY 2017 Worksheet S–10 data.

Step 5: For providers that did not report a CCR on Worksheet S–10, Line 1, we would assign them the statewide average CCR as determined in step 3.

After completing the above steps, we propose to re-calculate the hospital's uncompensated care costs (Line 30) using the trimmed CCR (the statewide average CCR (urban or rural, as applicable)).

• Uncompensated Care Data Trim Methodology

After applying the CCR trim methodology, we note that there are rare situations where a hospital has potentially aberrant data that are unrelated to CCR. Therefore, we are proposing to continue the trim methodology for potentially aberrant UCC that was finalized in the FY 2019 and FY 2020 IPPS/LTCH PPS final rules. That is, if the hospital's uncompensated care costs for FY 2017 are an extremely high ratio (greater than 50 percent) of its total operating costs, we propose to determine the ratio of uncompensated care costs to the hospital's total operating costs from another available cost report, and to apply that ratio to the total operating expenses for the potentially aberrant fiscal year to determine an adjusted amount of uncompensated care costs. Specifically, if the FY 2017 cost report is determined to include potentially aberrant data, we are proposing that data from the FY 2018 cost report would be used for the ratio calculation. Thus, the hospital's uncompensated care costs for FY 2017 would be trimmed by multiplying its FY 2017 total operating costs by the ratio of uncompensated care costs to total operating costs from the hospital's FY 2018 cost report to calculate an estimate of the hospital's

uncompensated care costs for FY 2017 for purposes of determining Factor 3 for FY 2021.

However, because we have audited the FY 2017 Worksheet S–10 data for a number of hospitals, we believe it is necessary to modify the UCC data trim methodology for hospitals whose FY 2017 cost report has been audited. Because the UCC data for these hospitals have been subject to audit, we believe there is increased confidence that if high uncompensated care costs are reported by these audited hospitals, the information is accurate. Therefore, we no longer believe it is necessary to apply the trim methodology for these audited hospitals. That is, we would exclude hospitals that were part of the audits from the trim methodology for potentially aberrant UCC. For those hospitals that do not have audited Worksheet S–10 data, we propose to continue to apply the trim methodology as previously described.

- Summary of Proposed Methodology

In summary, for FY 2021, we are proposing to compute Factor 3 for each hospital using the following steps—

Step 1: Select the provider's longest cost report from its Federal fiscal year (FFY) 2017 cost reports. (Alternatively, in the rare case when the provider has no FFY 2017 cost report because the cost report for the previous Federal fiscal year spanned the FFY 2017 time period, the previous Federal fiscal year cost report would be used in this step.)

Step 2: Annualize the uncompensated care costs (UCC) from Worksheet S–10 Line 30, if the cost report is more than or less than 12 months. (If applicable, use the statewide average CCR (urban or rural) to calculate uncompensated care costs.)

Step 3: Combine adjusted and/or annualized uncompensated care costs for hospitals that merged using the proposed merger policy, discussed earlier.

Step 4: Calculate Factor 3 for Indian Health Service and Tribal hospitals and Puerto Rico hospitals using the low-income insured days proxy based on FY 2013 cost report data and the most recent available SSI ratio (or, for Puerto Rico hospitals, 14 percent of the hospital's FY 2013 Medicaid days). The denominator is calculated using the low-income insured days proxy data from all DSH eligible hospitals.

Step 5: Calculate Factor 3 for the remaining DSH eligible hospitals using annualized uncompensated care costs (Worksheet S–10 Line 30) based on FY 2017 cost report data (from Step 1, 2 or 3). The hospitals for which Factor 3 was calculated in Step 4 are excluded from this calculation.

We are proposing to amend the regulation at § 412.106 by adding a new paragraph (g)(1)(iii)(C)(*7*) to reflect the proposed methodology for computing Factor 3 for FY 2021. We are also proposing to add a new paragraph (g)(1)(iii)(C)(*8*) to reflect the proposal for all subsequent fiscal years to use the most recent available single year of audited Worksheet S–10 data to calculate Factor 3 for all eligible hospitals, except IHS and Tribal hospitals.

(e) Proposals Related to the per Discharge Amount of Interim Uncompensated Care Payments

Consistent with the policy adopted in FY 2014 and applied in each subsequent fiscal year, we are proposing to use a 3-year average of the number of discharges for a hospital to produce an estimate of the amount of the uncompensated care payment per discharge. Specifically, the hospital's total uncompensated care payment amount, is divided by the hospital's historical 3-year average of discharges computed using the most recent available data. The result of that calculation is a per discharge payment amount that will be used to make interim uncompensated care payments to each projected DSH eligible hospital. The interim uncompensated care payments made to the hospital during the fiscal year are reconciled following the end of the year to ensure that the final payment amount is consistent with the hospital's prospectively determined uncompensated care payment for the Federal fiscal year.

In response to our proposal in the FY 2020 IPPS/LTCH PPS proposed rule to continue to determine interim uncompensated care payments using a 3-year average of discharges, we received a comment expressing concern that discharge growth discrepancies create the risk of overpayments of interim uncompensated care payments and unstable cash flows for CMS, hospitals, and MA plans (84 FR 42373). Taking the commenter's concerns into consideration, for FY 2021, we are proposing a voluntary process through which a hospital may submit a request to its Medicare Administrative Contractor (MAC) for a lower per discharge interim uncompensated care payment amount, including a reduction to zero, once before the beginning of the Federal fiscal year and/or once during the Federal fiscal year. In conjunction with this request, the hospital would be required to provide supporting documentation demonstrating there would likely be a significant recoupment (for example, 10 percent or more of the hospital's total uncompensated care payment or at least $100,000) at cost report settlement if the per discharge amount were not lowered. For example, a hospital might submit documentation showing a large projected increase in discharges during the fiscal year to support reduction of its per discharge uncompensated care payment amount. As another example, a hospital might request that its per discharge uncompensated care payment amount be reduced to zero midyear if the hospital's interim uncompensated care payments during the year have already surpassed the total uncompensated care payment calculated for the hospital.

We are proposing that the hospital's MAC would evaluate these requests and the supporting documentation before the beginning of the Federal fiscal year and/or with midyear requests when the 3-year average of discharges is lower than hospital's projected FY 2021 discharges. If following review of the request and the supporting documentation, the MAC agrees that there likely would be significant recoupment of the hospital's interim Medicare uncompensated care payments at cost report settlement, the only change that would be made would be to lower the per discharge amount either to the amount requested by the hospital or another amount determined by the MAC to be appropriate to reduce the likelihood of a substantial recoupment at cost report settlement. No change would be made to the total uncompensated care payment amount determined for the hospital on the basis of its Factor 3. In other words, this proposal does not change how the total uncompensated care payment amount will be reconciled at cost report settlement.

(f) Process for Notifying CMS of Merger Updates and To Report Upload Issues

As we have done for every proposed and final rule beginning in FY 2014, in conjunction with both the FY 2021 IPPS/LTCH PPS proposed rule and final rule, we will publish on the CMS website a table listing Factor 3 for all hospitals that we estimate would receive empirically justified Medicare DSH payments in FY 2021 (that is, those hospitals that would receive interim uncompensated care payments during the fiscal year), and for the remaining subsection (d) hospitals and subsection (d) Puerto Rico hospitals that have the potential of receiving a Medicare DSH payment in the event that they receive an empirically justified Medicare DSH payment for the fiscal year as

determined at cost report settlement. We note that, at the time of development of the proposed rule, the FY 2018 SSI ratios were available. Accordingly, for purposes of the proposed rule, we computed Factor 3 for Indian Health Service and Tribal hospitals and Puerto Rico hospitals using the most recent available data regarding SSI days from the FY 2018 SSI ratios.

We also will publish a supplemental data file containing a list of the mergers that we are aware of and the computed uncompensated care payment for each merged hospital.

Hospitals have 60 days from the date of public display of this FY 2021 IPPS/LTCH PPS proposed rule to review the table and supplemental data file published on the CMS website in conjunction with this proposed rule and to notify CMS in writing of issues related to mergers and/or to report potential upload discrepancies due to MAC mishandling of the Worksheet S–10 data during the report submission process (for example, report not reflecting audit results due to MAC mishandling or most recent report differs from previously accepted amended report due to MAC mishandling). Comments raising issues that are specific to the information included in the table and supplemental data file can be submitted to the CMS DSH inbox at *Section3133DSH@cms.hhs.gov*. All other comments submitted in response to our proposed policies for determining uncompensated care payments for FY 2021 must be submitted in one of three ways found in the **ADDRESSES** section of this proposed rule before the close of the comment period in order to be assured consideration. In addition, this CMS DSH inbox is not intended for Worksheet S–10 audit process related emails, which should be directed to the MACs. We will address comments related to mergers and/or reporting upload discrepancies submitted to the CMS DSH inbox as appropriate in the table and the supplemental data file that we publish on the CMS website in conjunction with the publication of the FY 2021 IPPS/LTCH PPS final rule.

For FY 2021, we are proposing that after the publication of the FY 2021 IPPS/LTCH PPS final rule, hospitals would have 15 business days from the date of public display of the FY 2021 IPPS/LTCH PPS final rule to review and submit comments on the accuracy of the table and supplemental data file published in conjunction with the final rule. Any changes to Factor 3 will be posted on the CMS website prior to October 1, 2020. We acknowledge that this is less time compared to previous years. However, there is only a limited amount of time to review the information submitted by the hospitals and to implement the finalized policies before the start of the Federal fiscal year. In general, we believe hospitals will have sufficient opportunity during the proposed rule's comment period to provide information about recent and/or pending mergers and/or to report upload discrepancies. We currently expect to use data from the March 2020 HCRIS extract for the FY 2021 final rule, which contributes to our increased confidence that hospitals will be able to comment on mergers and report any upload discrepancies during the comment period for this proposed rule. As noted earlier in this section, for purposes of calculating final Factor 3 in the FY 2021 IPPS/LTCH PPS final rule, we may also consider using more recent data that may become available after March 2020, but before the final rule. In the event that there are any remaining merger updates and/or upload discrepancies after the final rule, the 15 business days from the date of public display of the FY 2021 IPPS/LTCH PPS final rule deadline should allow for the time necessary to prepare and make any corrections to Factor 3 calculations before the beginning of the Federal fiscal year. In addition, we intend to revisit in future rulemaking whether to discontinue this additional comment process after the final rule, because we believe, in general, the comment period on the proposed rule should provide sufficient opportunity for hospitals to notify CMS regarding pending mergers and/or to report upload discrepancies.

We are inviting public comments on our proposed methodology for calculating Factor 3 for FY 2021, including, but not limited to, our proposed use of FY 2017 Worksheet S–10 data. In addition, we also request public comments on our proposal to calculate Factor 3 for all subsequent fiscal years and for all eligible hospitals, except Indian Health Service and Tribal hospitals, using the most recent available single year of audited Worksheet S–10 data. We are also seeking comments on the potential use of our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to restructure the DSH and uncompensated care payments to IHS and Tribal hospitals for FY 2022 and subsequent fiscal years, as described earlier.

H. Proposed Payment for Allogeneic Hematopoietic Stem Cell Acquisition Costs (§ 412.113)

1. Background

Medicare reimburses allogeneic hematopoietic stem cell transplants provided to Medicare beneficiaries for the treatment of certain diagnoses if such treatment is considered reasonable and necessary. Allogeneic hematopoietic stem cell transplants involve collecting or acquiring stem cells from a healthy donor's bone marrow, peripheral blood, or cord blood for intravenous infusion to the recipient. Currently, acquisition costs associated with allogeneic hematopoietic stem cell transplants are included in the operating costs of inpatient hospital services for subsection (d) hospitals (that is, hospitals paid under the IPPS). In addition, IPPS payments for acquisition services associated with allogeneic hematopoietic stem cell transplants are currently included in the MS–DRG payments for the allogeneic hematopoietic stem cell transplants when the transplants occurred in the inpatient setting.

Section 108 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94), provides that, effective for cost reporting periods beginning on or after October 1, 2020, costs related to hematopoietic stem cell acquisition for the purpose of an allogeneic hematopoietic stem cell transplant are not included in the definition of ''operating costs of inpatient hospital services'' at section 1886(a)(4) of the Act. In addition, section 108 of the Further Consolidated Appropriations Act, 2020 provides that in the case of a subsection (d) hospital that furnishes an allogeneic hematopoietic stem cell transplant, payment to such hospital for hematopoietic stem cell acquisition shall be made on a reasonable cost basis, and that the Secretary shall specify the items included in such hematopoietic stem cell acquisition in rulemaking. Section 108 of the Further Consolidated Appropriations Act, 2020, also requires that, beginning in FY 2021, the payments made based on reasonable cost for the acquisition costs of allogeneic hematopoietic stem cells be made in a budget neutral manner. We discuss each of the amendments under section 108 of the Further Consolidated Appropriations Act, 2020, and our proposed codification and implementation of those amendments, in the sections that follow.

2. Proposed Revisions to the Regulations for the Payment for Allogeneic Hematopoietic Stem Cell Acquisition Costs

a. Payment for Allogeneic Hematopoietic Stem Cell Acquisition Costs on a Reasonable Cost Basis

Division N, Section 108 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94) amended section 1886(d)(5) of the Act by adding a new paragraph (M)(i) which requires that, for cost reporting periods beginning on or after October 1, 2020, in the case of a subsection (d) hospital that furnishes an allogeneic hematopoietic stem cell transplant to an individual during such a period, payment to such hospital for hematopoietic stem cell acquisition shall be made on a reasonable cost basis. We are proposing to amend 42 CFR 412.113 to reflect this new statutory requirement by adding a new paragraph (e). This proposed new paragraph (e) states that for cost reporting periods beginning on or after October 1, 2020, in the case of a subsection (d) hospital that furnishes an allogeneic hematopoietic stem cell transplant to an individual, Medicare payment to such hospital for hematopoietic stem cell acquisition costs is made on a reasonable cost basis. This is the same way hospitals with approved transplant centers are reimbursed for their acquisition costs for solid organs under 42 CFR 412.113(d).

We are proposing to add new paragraph (e)(3) to 42 CFR 412.113 to specify that a subsection (d) hospital that furnishes allogeneic hematopoietic stem cell transplants be required to formulate a standard acquisition charge. The hospital's standard acquisition charge is based on costs expected to be reasonably and necessarily incurred in the acquisition of hematopoietic stem cells. The standard acquisition charge does not represent the cost of acquiring stem cells for an *individual* allogeneic hematopoietic stem cell transplant; rather, it is a charge that approximates the hospital's average cost of acquiring hematopoietic stem cells for *all* of its allogeneic hematopoietic stem cell transplants. We are proposing that the standard acquisition charge would be billed and paid on an interim payment basis as a ''pass-through'' item in accordance with 42 CFR 413.60 and 413.64. The actual charges by ancillary cost center from the provider's records would be included on the Medicare cost report and converted to reasonable cost using the corresponding ancillary cost-to-charge ratios. At the end of the cost reporting period, a settlement determination would be made of the actual cost incurred compared to the interim payments made during the period.

We are proposing to add new paragraph (e)(5) to 42 CFR 412.113 to specify that a subsection (d) hospital maintain an itemized statement that identifies the services furnished in collecting hematopoietic stem cells, the charges, the person receiving the service (donor/recipient, if donor the provider must identify the prospective recipient), and the recipient's health care insurance number.

We are proposing to add new paragraph (e)(4) to 42 CFR 412.113 to specify that the hospital's Medicare share of the hematopoietic stem cell acquisition costs is based on the ratio of the number of its allogeneic hematopoietic stem cell transplants furnished to Medicare beneficiaries to the total number of its allogeneic hematopoietic stem cell transplants furnished to all patients, regardless of payer, applied to reasonable cost. This is the same methodology used to reimburse transplant hospitals with approved transplant programs for their acquisition costs for solid organs, and will be further discussed in a forthcoming Paperwork Reduction Act (PRA) package as referenced in section IV.H.3. of this proposed rule.

In addition, we are proposing to amend 42 CFR 412.1(a) to reflect the new statutory requirement by revising the parenthetical identifying other costs related to inpatient hospital services that are paid for on a reasonable cost basis to include costs related to hematopoietic stem cell acquisition for the purpose of an allogeneic hematopoietic stem cell transplant. In addition, we are proposing to make formatting changes to 42 CFR 412.1(a) to improve the readability of this paragraph. We are also proposing to add new paragraph (e)(6) to 42 CFR 412.2 to add the costs of hematopoietic stem cell acquisition for the purpose of an allogeneic hematopoietic stem cell transplant to the list of services which are paid for on a reasonable cost basis.

b. Definition of Allogeneic Hematopoietic Stem Cell Transplant

Division N, Section 108 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94) amended section 1886(d)(5) of the Act by adding a new paragraph (M)(ii) which defines the term 'allogeneic hematopoietic stem cell transplant' to mean, with respect to an individual, the intravenous infusion of hematopoietic cells derived from bone marrow, peripheral blood stem cells, or cord blood, but not including embryonic stem cells, of a donor to an individual that are or may be used to restore hematopoietic function in such individual having an inherited or acquired deficiency or defect. We are proposing to codify this definition by adding new paragraph (e)(1) to 42 CFR 412.113.

c. Items Included as Allogeneic Hematopoietic Stem Cell Acquisition Costs

As noted, Division N, Section 108 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94) amended section 1886(d)(5) of the Act by adding a new paragraph (M)(i), which also requires that the Secretary specify the items included as allogeneic hematopoietic stem cell acquisition costs through rulemaking. Allogeneic hematopoietic stem cell acquisition costs apply only to hematopoietic allogeneic stem cell transplants, for which stem cells are obtained from a donor (other than the recipient himself or herself). Specifically, we are proposing that allogeneic hematopoietic stem cell acquisition costs would include registry fees from a national donor registry described in 42 U.S.C. 274k, if applicable, for stem cells from an unrelated donor; tissue typing of donor and recipient; donor evaluation; physician pre-admission/pre-procedure donor evaluation services; costs associated with the collection procedure such as, general routine and special care services, procedure/operating room and other ancillary services, and apheresis services; post-operative/post-procedure evaluation of donor; and the preparation and processing of stem cells derived from bone marrow, peripheral blood stem cells, or cord blood (but not including embryonic stem cells). We are also proposing to codify this definition of allogeneic hematopoietic stem cell acquisition costs by adding new proposed paragraph (e)(2) to 42 CFR 412.113. We invite public comments on whether any additional items should be included in the final rule.

3. Clarification of Hospital Cost Reporting Instructions

In the CY 2017 Outpatient Prospective Payment System (OPPS) final rule that appeared in the November 14, 2016 **Federal Register** (81 FR 79587), we finalized the policy to update the Medicare hospital cost report (Form CMS–2552–10, OMB control number 0938–0050, expiration date March 31, 2022) by adding a new standard cost center, line 77 ''Allogeneic Stem Cell Acquisition'' to Worksheet A (and applicable worksheets) with the standard cost center code of ''07700''. The new cost center line was

established in order to record any acquisition costs related to allogeneic stem cell transplants as defined in Section 231.11, Chapter 4, of the Medicare Claims Processing Manual (Pub. 100–04) in order to develop an accurate estimate of allogeneic hematopoietic stem cell donor acquisition costs for future ratesetting for CY 2017 and subsequent years. Note there is a similar discussion of allogeneic stem cell acquisition costs when the transplant occurs in the inpatient setting found in the Medicare Claims Processing Manual (Pub 100–04), Chapter 3, Section 90.3.1. However, with the establishment of this line came additional challenges on how to reclassify expenses into the new cost center from routine and ancillary departments. In addition, we found inconsistencies in the reporting of costs and charges for allogeneic hematopoietic stem cell acquisition costs.

The current cost reporting instructions require providers to report on line 77, the acquisition costs for allogeneic stem cell transplants. Line 77 only allows providers to report direct expenses, and does not provide a method for determining other routine and ancillary costs that are part of the allogeneic stem cell acquisition costs. Some providers are reclassifying costs from routine and ancillary cost centers to line 77. However, this practice does not align costs and charges properly in accordance with the Provider Reimbursement Manual, 15–1, chapter 23, sections 2300, 2302.7 and 2302.8 (available online at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021929*.). In addition, in order to reimburse allogeneic hematopoietic stem cell acquisition costs on a reasonable cost basis as required by the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94), and to accommodate the reporting of both direct and indirect costs on line 77 as well as routine and ancillary costs associated with the acquisition of hematopoietic stem cells, we are modifying cost reporting forms and instructions. We are developing a worksheet similar to the Worksheet D–4 for solid organs that will allow providers to capture costs from line 77 as well as to report charges by routine and ancillary cost center and compute the related costs.

Changes to the forms and instructions will be described in more detail in a forthcoming Paperwork Reduction Act (PRA) package, with comment period. In addition, the forthcoming PRA package will address providers' requests for a standardized format for data collection as referenced in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41681 through 41684) and Worksheet S–10 modifications as referenced in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42375).

4. Budget Neutrality for the Reasonable Cost Based Payment for Allogeneic Hematopoietic Stem Cell Acquisition Costs

Section 108 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94) amended section 1886(d)(4)(C)(iii) of the Act to require that beginning with FY 2021, the reasonable cost based payments for allogeneic hematopoietic stem cell acquisition costs be made in a manner that assures that the aggregate IPPS payments for discharges in the fiscal year are not greater or less than those that would have been made without such payments; that is, that the reasonable cost based payments for allogeneic hematopoietic stem cell acquisition costs be made in a budget neutral manner.

To implement this requirement, we are proposing to make an adjustment to the standardized amount to ensure the effects of the additional payments for allogeneic hematopoietic stem cell acquisition costs are budget neutral, as required under section 108 of Public Law 116–94. We are also proposing to codify this budget neutrality requirement by adding new paragraph (e)(5) to 412.64 to specify that CMS makes an adjustment to the standardized amount to ensure that the reasonable cost based payments for allogeneic hematopoietic stem cell acquisition costs are made in a manner so that aggregate payments to hospitals are not affected.

When the allogeneic stem cell transplant occurs in the inpatient setting, the hospital identifies stem cell acquisition charges for allogeneic hematopoietic stem cell transplants separately using revenue code 0815 on the inpatient hospital bill (see Medicare Claims Processing Manual, CMS Pub. 100–04, Chapter 3, section 90.3.1.B., which is available online at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03pdf.pdf*). To estimate the reasonable cost based payments for allogeneic hematopoietic stem cell acquisition costs for purposes of the proposed budget neutrality adjustment, we used the charges reported on the hospital's inpatient claim in revenue center code 0815 (which is reflected in the MedPAR field for the Revenue Center Allogeneic Stem Cell Acquisition/Donor Services) and converted those charges to costs by applying the hospital's operating cost-to-charge ratio (CCR) (that is, the same hospital-specific CCR used to estimate the hospital's operating outlier payments).

Based on the latest data for this proposed rule (claims from the December 2019 update of the FY 2019 MedPAR file and CCRs from the December 2019 update of the PSF), we estimate that reasonable cost based payments for allogeneic hematopoietic stem cell acquisition costs for FY 2021 would be $15,865,373.61. Therefore, the total amount that we are proposing to use to make an adjustment to the standardized amounts to ensure the additional payments for allogeneic hematopoietic stem cell acquisition costs are budget neutral is $15,865,373.61. We are further proposing that if more recent data become available for the final rule, we would use that data to determine the final amount we would use to make the budget neutrality adjustment. (We refer readers to section II.A.4.f. of the Addendum of this proposed rule for discussion of the budget neutrality adjustment factor we are proposing to apply to the standardized amounts for FY 2021 based on these estimated allogeneic hematopoietic stem cell acquisition costs.)

I. Proposed Payment Adjustment for CAR T-cell Clinical Trial Cases (§§ 412.85 and 412.312)

As discussed in section II.D.2.b. of the preamble of this proposed rule, we are proposing to create new MS–DRG 018 for cases that include procedures describing CAR T-cell therapies, which are currently reported using ICD–10–PCS procedure codes XW033C3 or XW043C3. As a requestor noted, a large percentage of the total cases that would group to any new MS–DRG for CAR T-cell therapy cases would be clinical trial cases, in which the provider typically does not incur the cost of the drug. By comparison, for non-clinical trial cases involving CAR T-cell therapy, the drug cost is an extremely large portion of the total costs. To address this, as described in section II.E.2.b. of this proposed rule, we are proposing to modify our relative weight methodology for proposed new MS–DRG 018 in order to develop a relative weight that is reflective of the typical costs of providing CAR T-cell therapies relative to other IPPS services. Specifically, in determining the relative weights, we are proposing that clinical trial claims that group to proposed new MS–DRG 018 would not be included when calculating the average cost for

proposed new MS–DRG 018 that is used to calculate the relative weight for this MS–DRG, so that the relative weight reflects the costs of the CAR T-cell therapy drug. For additional details on the proposed modifications to our relative weight methodology relating to clinical trial cases involving CAR–T cell therapy, we refer readers to section II.E.2.b. of this proposed rule.

Cases involving clinical trials, like non-clinical trial cases, are currently paid using the relative weight for the MS–DRG to which the case is assigned. However, given that the drug cost is an extremely large portion of the total costs of the non-clinical trial CAR T-cell therapy cases, and that the relative weight for proposed new MS–DRG 018 assumes that the provider has incurred the costs of the CAR T-cell therapy drug, we are proposing to apply an adjustment to the payment amount for clinical trial cases that would group to proposed new MS–DRG 018. We are proposing to calculate this proposed adjustment using the same methodology that we are proposing to use to adjust the case count for purposes of the relative weight calculations:

- Calculate the average cost for cases to be assigned to proposed new MS–DRG 018 that contain ICD–10–CM diagnosis code Z00.6 or contain standardized drug charges of less than $373,000.
- Calculate the average cost for cases to be assigned to proposed new MS–DRG 018 that do not contain ICD–10–CM diagnosis code Z00.6 or standardized drug charges of at least $373,000.
- Calculate an adjustor by dividing the average cost calculated in step 1 by the average cost calculated in step 2.
- Apply this adjustor when calculating payments for clinical trial cases that group to MS–DRG 018 by multiplying the relative weight for MS–DRG 018 by the adjustor.

Consistent with our methodology for calculating the proposed case count adjustment for purposes of the relative weight calculations, for FY 2021, for purposes of calculating this proposed payment adjustment, we identified clinical trial claims as claims that contain ICD–10–CM diagnosis code Z00.6 (Encounter for examination for normal comparison and control in clinical research program) or contain standardized drug charges of less than $373,000.

For FY 2021, based on the claims data from the December 2019 update of the FY 2019 MedPAR files used for this proposed rule, the ratio of the average cost for CAR T-cell therapy cases identified as clinical trial cases to the average cost for non-clinical trial CAR T-cell therapy cases (that is, those cases not identified as being clinical trial cases) is 0.15. Therefore, we are proposing that the adjustor that would be applied to CAR T-cell therapy clinical trial cases would be 0.15. For example, if the relative weight for proposed new MS–DRG 018 is 30.00, we would multiply 30.00 by the adjustor of 0.15 as part of the calculation of the payment for clinical trial claims assigned to proposed new MS–DRG 018.

The clinical trial cases involving CAR T-cell therapy that would be subject to this proposed adjustment would be those cases that would group to proposed new MS–DRG 18 and include ICD–10–CM diagnosis code Z00.6 (Encounter for examination for normal comparison and control in clinical research program). ICD–10–CM diagnosis code Z00.6 is required to be included with clinical trial cases and we expect hospitals to include this code for clinical trial cases that would group to proposed MS–DRG 18 for FY 2021 and all subsequent years. Consistent with our historical practice, we are also proposing to update the value of the adjustor based on more recent data for the final rule.

We are also proposing to amend our regulations at 42 CFR part 412, subpart F (for operating IPPS payments), and 42 CFR 412.312 (for capital IPPS payments) to codify this proposed payment adjustment for certain clinical trial cases. Under 42 CFR part 412, subpart F, we are proposing to redesignate existing § 412.86 (which sets forth payment for extraordinarily high-cost day outliers for discharges occurring before October 1, 1997) as new § 412.83, and to add a new center heading and new § 412.85 to codify the proposed payment adjustment for certain clinical trial cases. We are also proposing to make conforming changes to § 412.82(c) to replace the reference to § 412.86 with § 412.83, and proposing to reserve § 412.86. We are proposing this restructuring to subpart F in order to keep the sections related to payment for outlier cases together under the ''Payment for Outlier Cases'' center heading when adding the proposed section to codify the proposed payment adjustment for certain clinical trial cases. Specifically, proposed new § 412.85 provides for a payment adjustment for a discharge assigned to MS–DRG 018 that is part of a clinical trial as determined by CMS based on the reporting of a diagnosis code indicating the encounter is part of a clinical research program on the claim for the discharge. Proposed new § 412.85 further provides that payment for such a discharge is adjusted by adjusting the DRG weighting factor determined under § 412.60(b) by a factor that reflects the average cost for cases to be assigned to MS–DRG 018 that are part of a clinical trial to the average cost for cases to be assigned to MS–DRG 018 that are not part of a clinical trial. Similarly, we are proposing to add paragraph (f) to § 412.312 to specify that in determining the capital IPPS payments under that section for certain clinical trial cases as described in § 412.85(b), the DRG weighting factor described in § 412.312(b)(1) is adjusted as described in § 412.85(c).

We are inviting public comments on our proposals.

J. Proposed Changes for Hospitals With High Percentage of End Stage Renal Disease (ESRD) Discharges (§ 412.104)

Under § 412.104(a), CMS provides an additional payment to a hospital for inpatient services provided to End Stage Renal Disease (ESRD) beneficiaries who receive a dialysis treatment during a hospital stay, if the hospital has established that ESRD beneficiary discharges, excluding discharges classified into MS–DRG 652 (Kidney Transplant), MS–DRG 682 (Renal Failure with MCC), MS–DRG 683 (Renal Failure with CC), MS–DRG 684 (Renal Failure without CC/MCC) and MS–DRG 685 (Admit for Renal Dialysis), where the beneficiary received dialysis services during the inpatient stay, constitute 10 percent or more of its total Medicare discharges. (We note that in existing § 412.104(a), the title of MS DRG 652 is mistakenly shown as ''Renal Failure'' instead of ''Kidney Transplant''.)

As discussed in section II.D.8.a. of the preamble of this proposed rule, for FY 2021, we are proposing to create a new Pre-MDC MS–DRG for cases describing the performance of hemodialysis during an admission where the patient received a simultaneous pancreas/kidney transplant. We are also proposing to create two new MS–DRGs with a two-way severity level split for cases describing the performance of hemodialysis in an admission where the patient received a kidney transplant in MDC 11. These proposed new MS–DRGs are proposed new MS–DRG 019 (Simultaneous Pancreas/Kidney Transplant with Hemodialysis), proposed new MS–DRG 650 (Kidney Transplant with Hemodialysis with MCC), and proposed new MS–DRG 651 (Kidney Transplant with Hemodialysis without MCC). The relative weights for these proposed MS–DRGs reflect the resources related to the provision of inpatient hemodialysis. Accordingly, we

believe that discharges classified to these proposed new MS–DRGs should be excluded in determining a hospital's eligibility for the additional payment for hospitals with high percentages of ESRD discharges and, therefore, are proposing to add MS–DRGs 019, 650, and 651 to the list of excluded MS–DRGs set forth in § 412.104(a). Furthermore, under the proposed MS–DRG logic for kidney transplants, a case with a hemodialysis procedure reported on the claim would no longer group to MS–DRG 652 (Kidney Transplant). We also note that MS–DRG 685 (Admit for Renal Dialysis) was deleted effective FY 2019 (83 FR 41201 through 41202). Therefore, we are proposing to remove MS–DRGs 652 and 685 from the list of excluded MS–DRGs set forth in § 412.104(a).

We are proposing to revise § 412.104(a) to reflect these proposed changes to the MS–DRG logic for kidney transplants and the previous deletion of MS–DRG 685. We are also proposing to make formatting changes to this provision to list the MS–DRG exclusions.

K. Hospital Readmissions Reduction Program: Proposed Updates and Changes (§§ 412.150 Through 412.154)

1. Statutory Basis for the Hospital Readmissions Reduction Program

Section 1886(q) of the Act, as amended by section 15002 of the 21st Century Cures Act, establishes the Hospital Readmissions Reduction Program. Under the Hospital Readmissions Reduction Program, Medicare payments under the acute inpatient prospective payment system for discharges from an applicable hospital, as defined under section 1886(d) of the Act, may be reduced to account for certain excess readmissions. Section 15002 of the 21st Century Cures Act requires the Secretary to compare hospitals with respect to the proportion of beneficiaries who are dually eligible for Medicare and full-benefit Medicaid (dual eligibles) in determining the extent of excess readmissions. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49531) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38240) for a detailed discussion of and additional information on the statutory history of the Hospital Readmissions Reduction Program.

2. Regulatory Background

We refer readers to the following final rules for detailed discussions of the regulatory background and descriptions of the current policies for the Hospital Readmissions Reduction Program:

- FY 2012 IPPS/LTCH PPS final rule (76 FR 51660 through 51676).
- FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53401).
- FY 2014 IPPS/LTCH PPS final rule (78 FR 50649 through 50676).
- FY 2015 IPPS/LTCH PPS final rule (79 FR 50024 through 50048).
- FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49543).
- FY 2017 IPPS/LTCH PPS final rule (81 FR 56973 through 56979).
- FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38240).
- FY 2019 IPPS/LTCH PPS final rule (83 FR 41431 through 41439).
- FY 2020 IPPS/LTCH PPS final rule (84 FR 42380 through 42390).

These rules describe the general framework for the implementation of the Hospital Readmissions Reduction Program, including: (1) The selection of measures for the applicable conditions/procedures; (2) the measure removal factors policy; (3) the calculation of the excess readmission ratio (ERR), which is used, in part, to calculate the payment adjustment factor; (4) the calculation of the proportion of ''dually eligible'' Medicare beneficiaries, which is used to stratify hospitals into peer groups and establish the peer group median ERRs; (5) the calculation of the payment adjustment factor, specifically addressing the base operating DRG payment amount, aggregate payments for excess readmissions (including calculating the peer group median ERRs), aggregate payments for all discharges, and the neutrality modifier; (6) the opportunity for hospitals to review and submit corrections using a process similar to what is currently used for posting results on *Hospital Compare* or its successor; (7) the adoption of an extraordinary circumstances exception policy to address hospitals that experience a disaster or other extraordinary circumstance; (8) the clarification that the public reporting of ERRs will be posted on an annual basis to the *Hospital Compare* website or its successor as soon as is feasible following the review and corrections period; and (9) the specification that the definition of ''applicable hospital'' does not include hospitals and hospital units excluded from the IPPS, such as LTCHs, cancer hospitals, children's hospitals, IRFs, IPFs, CAHs, and hospitals in United States territories and Puerto Rico.

We have also codified certain requirements of the Hospital Readmissions Reduction Program at 42 CFR 412.152 through 412.154. In section IV.K.11. of the preamble of this proposed rule, we are proposing to update the regulatory text to reflect the policies that we are proposing in this proposed rule.

3. Summary of Proposed Policies for the Hospital Readmissions Reduction Program

In section IV.K.6. of the preamble of this proposed rule, we are proposing the automatic adoption of applicable periods policy beginning with the FY 2023 program year and all subsequent program years, unless otherwise specified by the Secretary. In section IV.K.11. of the preamble of this proposed rule, we are proposing to update the definition of applicable period at 42 CFR 412.152 to align with this proposal.

We discuss these proposals in greater detail in this rule.

4. Current Measures for FY 2021 and Subsequent Years

The Hospital Readmissions Reduction Program currently includes six applicable conditions/procedures: Acute myocardial infarction (AMI); heart failure (HF); pneumonia; elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA); chronic obstructive pulmonary disease (COPD); and coronary artery bypass graft (CABG) surgery.

We continue to believe the measures we have adopted adequately meet the goals of the Hospital Readmissions Reduction Program. Therefore, we are not proposing to remove or adopt any additional measures at this time.

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41431 through 41439) for more information about how the Hospital Readmissions Reduction Program supports CMS' goal of bringing quality measurement, transparency, and improvement together with value-based purchasing to the hospital inpatient care setting through the Meaningful Measures Initiative.

5. Definition of ''Dual-Eligible'' Beginning in FY 2021 and for Subsequent Years

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226 through 38229), as part of implementing the 21st Century Cures Act, we finalized the definition of dual-eligible as follows: ''[A]n individual would be counted as a full-benefit dual patient if the beneficiary was identified as full-benefit dual status in the State [Medicare Modernization Act] (MMA) files for the month he/she was discharged from the hospital.'' In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41437 through 41438), we codified this definition at 42 CFR 412.152 along with other definitions

pertinent to dual-eligibility calculations for assigning hospitals into peer groups. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42384 through 42385), we finalized an update to the definition of ''dual-eligible'' to specify that, for the payment adjustment factors beginning with the FY 2021 program year, ''dual-eligible'' is a patient beneficiary who has been identified as having full benefit status in both the Medicare and Medicaid programs in data sourced from the State MMA files for the month the beneficiary was discharged from the hospital, except for those patient beneficiaries who die in the month of discharge, who will be identified using the previous month's data sourced from the State MMA files.

The updated definition accounts for misidentification of the dual-eligible status of patient beneficiaries who die in the month of discharge, which can occur under the previous definition. We estimated that the number of misidentified patient beneficiaries was very small, and our analysis showed that this very small total increase did not have a large impact on peer grouping assignments or payment adjustments. We remind readers that we finalized this updated definition for FY 2021 and for subsequent program years. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42384 through 42385) for a more detailed discussion of this topic. We are not proposing any updates to our definition of ''dual-eligible'' beneficiaries in this proposed rule.

6. Proposed Automatic Adoption of Applicable Periods for FY 2023 and Subsequent Years

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51671) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53375) for discussion of our previously finalized policy for defining applicable periods. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41434 through 41435) and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42387), we finalized the following ''applicable periods'' consistent with the definition specified at 42 CFR412.152, to calculate the readmission payment adjustment factor for FY 2021 and FY 2022, respectively:

- The 3-year time period of July 1, 2016 through June 30, 2019 for FY 2021.
- The 3-year time period of July 1, 2017 through June 30, 2020 for FY 2022.

This is the 3-year period from which data are being collected in order to calculate ERRs and payment adjustment factors for the fiscal year; this includes aggregate payments for excess readmissions and aggregate payments for all discharges used in the calculation of the payment adjustment. The ''applicable period'' for dual eligibles is the same as the ''applicable period'' that we otherwise adopt for purposes of the Hospital Readmissions Reduction Program.

We continue to believe that the 3-year period is the appropriate data collection period for the Hospital Readmissions Reduction Program measures. In order to provide greater certainty around future applicable periods for the Hospital Readmissions Reduction Program, we are proposing the automatic adoption of applicable periods for FY 2023 and all subsequent program years for the Hospital Readmissions Reduction Program. Beginning in FY 2023, the applicable period for the Hospital Readmissions Reduction Program will be the 3-year period beginning 1 year advanced from previous program fiscal year's start of the applicable period. That is, for FY 2023, the applicable period for the Hospital Readmissions Reduction Program measures and for determining dual eligibility will be the 3-year period from July 1, 2018 through June 30, 2021, which is advanced 1 year from the applicable period for the FY 2022 Hospital Readmissions Reduction Program. Under this proposed policy, for all subsequent years, we would advance this 3-year period by 1 year unless otherwise specified by the Secretary, which we would convey through notice and comment rulemaking. Similarly, the applicable period for dual eligibility would continue to correspond to the applicable period for the Hospital Readmissions Reduction Program, unless otherwise specified by the Secretary. We believe that the automatic adoption of the applicable period each year will streamline the process and provide additional clarity and consistency to the Program.

7. Identification of Aggregate Payments for Each Condition/Procedure and All Discharges for FY 2021

When calculating the numerator (aggregate payments for excess readmissions), we determine the base operating DRG payment amount for an individual hospital for the applicable period for each condition/procedure using Medicare inpatient claims from the MedPAR file with discharge dates that are within the applicable period. Under our established methodology, we use the update of the MedPAR file for each Federal fiscal year, which is updated 6 months after the end of each Federal fiscal year within the applicable period, as our data source.

In identifying discharges for the applicable conditions/procedures to calculate the aggregate payments for excess readmissions, we apply the same exclusions to the claims in the MedPAR file as are applied in the measure methodology for each of the applicable conditions/procedures. For the FY 2021 applicable period, this includes the discharge diagnoses for each applicable condition/procedure based on a list of specific ICD–10–CM and ICD–10–PCS code sets, as applicable, for that condition/procedure, because diagnoses and procedure codes for discharges occurring on or after October 1, 2015 (FY 2016) began reporting under the ICD–10–CM and ICD–10–PCS code sets as opposed to the previous ICD–9–CM code set.

We identify Medicare fee-for-service (FFS) claims that meet the criteria as previously described for each applicable condition/procedure to calculate the aggregate payments for excess readmissions. This means that claims paid for under Medicare Part C (Medicare Advantage) are not included in this calculation. This policy is consistent with the methodology to calculate ERRs based solely on admissions and readmissions for Medicare FFS patients. Therefore, consistent with our established methodology, for FY 2021, we are proposing to continue to exclude admissions for patients enrolled in Medicare Advantage (MA), as identified in the Medicare Enrollment Database.

In this proposed rule, for FY 2021, we are proposing to determine aggregate payments for excess readmissions, and aggregate payments for all discharges using data from MedPAR claims with discharge dates that align with the FY 2021 applicable period. As we stated in FY 2018 IPPS/LTCH PPS final rule (82 FR 38232), we will determine the neutrality modifier using the most recently available full year of MedPAR data. However, we note that, for the purpose of modeling the proposed FY 2021 readmissions payment adjustment factors for this proposed rule, we are using the proportion of dual-eligibles, excess readmission ratios, and aggregate payments for each condition/procedure and all discharges for applicable hospitals from the FY 2020 Hospital Readmissions Reduction Program applicable period. For the FY 2021 program year, applicable hospitals will have the opportunity to review and correct calculations based on the proposed FY 2021 applicable period of July 1, 2016 to June 30, 2019, before they are made public under our policy regarding reporting of hospital-specific information. Again, we reiterate that

this period is intended to review the program calculations, and not the underlying data. For more information on the review and corrections process, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53399 through 53401).

In this proposed rule, we are proposing to continue to use MedPAR data corresponding to the applicable period for the Hospital Readmissions Reduction Program calculations. We are proposing to use the March update of the fiscal year MedPAR to identify discharges within the applicable period during that fiscal year.

8. Calculation of Payment Adjustment Factors for FY 2021

As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226), section 1886(q)(3)(D) of the Act requires the Secretary to group hospitals and apply a methodology that allows for separate comparisons of hospitals within peer groups in determining a hospital's adjustment factor for payments applied to discharges beginning in FY 2019.

We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38226 through 38237) for a detailed discussion of the payment adjustment methodology. In the FY 2021 IPPS/LTCH PPS proposed rule, we are not proposing any changes to this payment adjustment calculation methodology for FY 2021.

9. Calculation of Payment Adjustment for FY 2021

Section 1886(q)(3)(A) of the Act defines the payment adjustment factor for an applicable hospital for a fiscal year as ''equal to the greater of: (i) the ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or (ii) the floor adjustment factor specified in subparagraph (C).'' Section 1886(q)(3)(B) of the Act, in turn, describes the ratio used to calculate the adjustment factor. Specifically, it states that the ratio is equal to 1 minus the ratio of—(1) the aggregate payments for excess readmissions; and (2) the aggregate payments for all discharges, scaled by the neutrality modifier. The calculation of this ratio is codified at 42 CFR 412.154(c)(1) and the floor adjustment factor is codified at 42 CFR 412.154(c)(2). Section 1886(q)(3)(C) of the Act specifies the floor adjustment factor at 0.97 for FY 2015 and subsequent fiscal years.

Consistent with section 1886(q)(3) of the Act, codified in our regulations at 42 CFR 412.154(c)(2), for FY 2021, the payment adjustment factor will be either the greater of the ratio or the floor adjustment factor of 0.97. Under our established policy, the ratio is rounded to the fourth decimal place. In other words, for FY 2021, a hospital subject to the Hospital Readmissions Reduction Program would have an adjustment factor that is between 1.0 (no reduction) and 0.9700 (greatest possible reduction).

For additional information on the FY 2021 payment calculation, we refer readers to the Hospital Readmissions Reduction Program information and resources available on our QualityNet website. We are not proposing any changes to our calculation of payment methodology in this proposed rule.

10. Confidential Reporting of Stratified Data for Hospital Quality Measures

Consistent with our plans described in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42388 through 42390), we will include in confidential hospital-specific reports (HSR) data stratified by patient dual-eligible status for the six readmissions measures included in the Hospital Readmissions Reduction Program in the Spring of 2020. These data will include two disparity methodologies designed to illuminate potential disparities within individual hospitals and across hospitals nationally and will supplement the measure data currently publicly reported on the *Hospital Compare* website. However, this stratified data would be in confidential reports and not publicly reported at this time. The first methodology, the Within-Hospital Disparity Method, highlights differences in outcomes for dual-eligible versus non-dual-eligible patients within an individual hospital, while the second methodology, the Dual Eligible Outcome Method, allows for a comparison of performance in care for dual-eligible patients across hospitals (82 FR 38405 through 38407; 83 FR 41598; 84 FR 42388 through 42389). These two disparity methods are separate from the methodology used by the Hospital Readmissions Reduction Program that assesses hospital performance relative to other hospitals with a similar proportion of dual-eligible patients (that is, peer group), and we emphasize that the two disparity methods would not be used in payment adjustment factor calculations under the Hospital Readmissions Reduction Program.

We note that the two disparity methods do not place any additional collection or reporting burden on hospitals because dual-eligibility data are readily available in claims data. In addition, we reiterate that these confidential hospital-specific reports data do not impact the calculation of hospital payment adjustment factors under the Hospital Readmissions Reduction Program.

We are not proposing any updates to the confidential reporting of stratified data in this proposed rule.

11. Proposed Regulatory Revisions

We are proposing to revise 42 CFR 412.152 to reflect the proposed policy to automatically adopt applicable periods for the Program, as previously discussed in section IV.K.6. of the preamble of this proposed rule. Specifically, we are proposing to revise the definition of ''applicable period'' and ''applicable period for dual-eligibility'' as follows:

Applicable period is, with respect to a fiscal year, the 3-year period (specified by the Secretary) from which data are collected in order to calculate excess readmission ratios and adjustments under the Hospital Readmissions Reduction Program. The applicable period for FY 2022 is the 3-year period from July 1, 2017 through June 30, 2020. Beginning with the FY 2023 program year, the applicable period is the 3-year period advanced by 1-year from the prior year's period from which data are collected in order to calculate excess readmission ratios and adjustments under the Hospital Readmissions Reduction Program, unless otherwise specified by the Secretary. That is, the applicable period for FY 2023 is the 3-year period from July 1, 2018 through June 30, 2021.

Applicable period for dual-eligibility is the 3-year data period corresponding to the applicable period for the Hospital Readmissions Reduction Program, unless otherwise established by the Secretary.

L. Hospital Value-Based Purchasing (VBP) Program: Updates

1. Background

a. Statutory Background and Overview of Past Program Years

Section 1886(o) of the Act requires the Secretary to establish a hospital value-based purchasing program (the Hospital VBP Program) under which value-based incentive payments are made in a fiscal year (FY) to hospitals that meet performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary.

For more of the statutory background and descriptions of our current policies for the Hospital VBP Program, we refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26490 through 26547); the FY 2012 IPPS/LTCH PPS final rule (76 FR 51653 through 51660);

the CY 2012 OPPS/ASC final rule with comment period (76 FR 74527 through 74547); the FY 2013 IPPS/LTCH PPS final rule (77 FR 53567 through 53614); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50676 through 50707); the CY 2014 OPPS/ASC final rule (78 FR 75120 through 75121); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50048 through 50087); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49544 through 49570); the FY 2017 IPPS/LTCH PPS final rule (81 FR 56979 through 57011); the CY 2017 OPPS/ASC final rule with comment period (81 FR 79855 through 79862); the FY 2018 IPPS/LTCH PPS final rule (82 FR 38240 through 38269); the FY 2019 IPPS/LTCH PPS final rule (83 FR 41440 through 41472); and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42390 through 42402).

We also have codified certain requirements for the Hospital VBP Program at 42 CFR 412.160 through 412.167.

b. FY 2021 Program Year Payment Details

Section 1886(o)(7)(B) of the Act instructs the Secretary to reduce the base operating DRG payment amount for a hospital for each discharge in a fiscal year by an applicable percent. Under section 1886(o)(7)(A) of the Act, the sum total of these reductions in a fiscal year must equal the total amount available for value-based incentive payments for all eligible hospitals for the fiscal year, as estimated by the Secretary. We finalized details on how we would implement these provisions in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), and we refer readers to that rule for further details.

Under section 1886(o)(7)(C)(v) of the Act, the applicable percent for the FY 2021 program year is 2.00 percent. Using the methodology we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), we estimate that the total amount available for value-based incentive payments for FY 2021 is approximately $1.9 billion, based on the December 2019 update of the FY 2019 MedPAR file. We intend to update this estimate in the FY 2021 IPPS/LTCH PPS final rule using the March 2020 update of the FY 2019 MedPAR file.

As finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53573 through 53576), we will utilize a linear exchange function to translate this estimated amount available into a value-based incentive payment percentage for each hospital, based on its Total Performance Score (TPS). We will then calculate a value-based incentive payment adjustment factor that will be applied to the base operating DRG payment amount for each discharge occurring in FY 2021, on a per-claim basis. We are publishing proxy value-based incentive payment adjustment factors in Table 16 associated with this proposed rule (which is available via the internet on the CMS website). The proxy factors are based on the TPSs from the FY 2020 program year. These FY 2020 performance scores are the most recently available performance scores hospitals have been given the opportunity to review and correct. The slope of the linear exchange function used to calculate the proxy value-based incentive payment adjustment factors in Table 16 is 2.8109876851. This slope, along with the estimated amount available for value-based incentive payments, is also published in Table 16.

We intend to update this table as Table 16A associated with the final rule (which will be available on the CMS website) to reflect changes based on the March 2020 update to the FY 2019 MedPAR file. We also intend to update the slope of the linear exchange function used to calculate those updated proxy value-based incentive payment adjustment factors. The updated proxy value-based incentive payment adjustment factors for FY 2021 will continue to be based on historic FY 2020 program year TPSs because hospitals will not have been given the opportunity to review and correct their actual TPSs for the FY 2021 program year until after the FY 2021 IPPS/LTCH PPS final rule is published.

After hospitals have been given an opportunity to review and correct their actual TPSs for FY 2021, we will post as Table 16B associated with the final rule (which will be available via the internet on the CMS website) the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the FY 2021 program year. We expect Table 16B will be posted on the CMS website in the Fall of 2020.

2. Retention and Removal of Quality Measures

a. Retention of Previously Adopted Hospital VBP Program Measures and Relationship Between the Hospital IQR and Hospital VBP Program Measure Sets

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53592), we finalized a policy to retain measures from prior program years for each successive program year, unless otherwise proposed and finalized. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41440 through 41441), we finalized a revision to our regulations at 42 CFR 412.164(a) to clarify that once we have complied with the statutory prerequisites for adopting a measure for the Hospital VBP Program (that is, we have selected the measure from the Hospital IQR Program measure set and included data on that measure on *Hospital Compare* or its successor for at least 1 year prior to its inclusion in a Hospital VBP Program performance period), the Hospital VBP Program statute does not require that the measure continue to remain in the Hospital IQR Program. We are not proposing any changes to these policies in this proposed rule.

b. Measure Removal Factors for the Hospital VBP Program

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41441 through 41446), in alignment with the Hospital IQR Program, we finalized measure removal factors for the Hospital VBP Program, and we refer readers to that final rule for details. We are not proposing any changes to these policies in this proposed rule.

c. Summary of Previously Adopted Measures for the FY 2023 and FY 2024 Program Years

We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42392 through 42393) for summaries of previously adopted measures for the FY 2022 and FY 2023 program years, and to the tables in this section showing summaries of previously adopted measures for the FY 2023 and FY 2024 program years. We note that we are not proposing to add new measures or remove measures from the Hospital VBP Program in this proposed rule.

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Summary of Previously Adopted Measures for the FY 2023 and FY 2024 Program Years		
Measure Short Name	**Domain/Measure Name**	**NQF #**
Person and Community Engagement Domain		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition Measure)	0166 (0228)
Safety Domain		
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CLABSI	National Healthcare Safety Network (NHSN) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure	1716
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure	1717
CMS PSI 90*	CMS Patient Safety and Adverse Events Composite*	0531
Clinical Outcomes Domain		
MORT-30-AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization	0230
MORT-30-HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization	0229
MORT-30-PN (updated cohort)	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization	0468
MORT-30-COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization	1893
MORT-30-CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery	2558
COMP-HIP-KNEE**	Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	1550
Efficiency and Cost Reduction Domain		
MSPB	Medicare Spending Per Beneficiary (MSPB) – Hospital	2158

* We note that in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42392 through 42393), we updated the name of the Patient Safety and Adverse Events Composite (PSI 90) to the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) when it is used in CMS programs due to transition of the measure from AHRQ to CMS.
** We note that in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42392 through 42393), we updated the short name of the Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) measure (NQF #1550) from THA/TKA to COMP-HIP-KNEE in order to maintain consistency with the updated Measure ID and short name used in tables on *Hospital Compare* and/or its successor and hospital reports for the Hospital VBP Program.

3. Previously Adopted Baseline and Performance Periods

a. Background

Section 1886(o)(4) of the Act requires the Secretary to establish a performance period for the Hospital VBP Program that begins and ends prior to the beginning of such fiscal year. We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56998 through 57003) for baseline and performance periods that we have adopted for the FY 2020, FY 2021, and FY 2022 program years. In the same final rule, we finalized a schedule for all future baseline and performance periods for previously adopted measures. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38256 through 38261), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41466 through 41469), and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42393 through 42395) for additional baseline and performance periods that we have adopted for the FY 2022, FY 2023, and subsequent program years.

b. Person and Community Engagement Domain

Since the FY 2015 program year, we have adopted a 12-month baseline period and a 12-month performance period for measures in the Person and Community Engagement domain (previously referred to as the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain) (77 FR 53598; 78 FR 50692; 79 FR 50072; 80 FR 49561). In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56998), we finalized our proposal to adopt a 12-month performance period for the Person and Community Engagement domain that runs on the calendar year 2 years prior to the applicable program year and a 12-month baseline period that runs on the calendar year 4 years prior to the applicable program year, for the FY 2019 program year and subsequent years.

We are not proposing any changes to these policies in this proposed rule.

c. Clinical Outcomes Domain

For the FY 2020 and FY 2021 program years, we adopted a 36-month baseline period and a 36-month performance period for measures in the Clinical Outcomes domain (previously referred to as the Clinical Care domain) (79 FR 50073; 80 FR 49563 through 49564). In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57001), we also adopted a 22-month performance period and a 36-month baseline period specifically for the MORT–30–PN (updated cohort) measure for the FY 2021 program year.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57000), we adopted a 36-month performance period and a 36-month baseline period for the FY 2022 program year for each of the previously finalized measures in the Clinical Outcomes domain—that is, the MORT–30–AMI, MORT–30–HF, MORT–30–COPD, COMP–HIP–KNEE, and MORT–30–CABG measures. In the same final rule (81 FR 57001), we adopted a 34-month performance period and a 36-month baseline period for the MORT–30–PN (updated cohort) measure for the FY 2022 program year.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38259), we adopted a 36-month performance period and a 36-month baseline period for the MORT–30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–CABG, MORT–30–PN (updated cohort), and COMP–HIP–KNEE measures for the FY 2023 program year and subsequent years. Specifically, for the mortality measures (MORT–30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–CABG, and MORT–30–PN (updated cohort)), the performance period runs for 36 months from July 1, 5 years prior to the applicable fiscal program year, to June 30, 2 years prior to the applicable fiscal program year, and the baseline period runs for 36 months from July 1, 10 years prior to the applicable fiscal program year, to June 30, 7 years prior to the applicable fiscal program year. For the COMP–HIP–KNEE measure, the performance period runs for 36 months from April 1, 5 years prior to the applicable fiscal program year, to March 31, 2 years prior to the applicable fiscal program year, and the baseline period runs for 36 months from April 1, 10 years prior to the applicable fiscal program year, to March 31, 7 years prior to the applicable fiscal program year.

We are not proposing any changes to the length of these performance or baseline periods in this proposed rule.

d. Safety Domain

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57000), we finalized our proposal to adopt a performance period for all measures in the Safety domain—with the exception of the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) measure—that runs on the calendar year 2 years prior to the applicable program year and a baseline period that runs on the calendar year 4 years prior to the applicable program year for the FY 2019 program year and subsequent program years.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38258), for the FY 2023 program year, we adopted a 21-month baseline period (October 1, 2015 to June 30, 2017) and a 24-month performance period (July 1, 2019 to June 30, 2021) for the CMS PSI 90 measure. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38258 through 38259), we adopted a 24-month performance period and a 24-month baseline period for the CMS PSI 90 measure for the FY 2024 program year and subsequent years. Specifically, the performance period runs from July 1, 4 years prior to the applicable fiscal program year, to June 30, 2 years prior to the applicable fiscal program year, and the baseline period runs from July 1, 8 years prior to the applicable fiscal program year, to June 30, 6 years prior to the applicable fiscal program year.

We are not proposing any changes to these policies in this proposed rule.

e. Efficiency and Cost Reduction Domain

Since the FY 2016 program year, we have adopted a 12-month baseline period and a 12-month performance period for the MSPB measure in the Efficiency and Cost Reduction domain (78 FR 50692; 79 FR 50072; 80 FR 49562). In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56998), we finalized our proposal to adopt a 12-month performance period for the MSPB measure that runs on the calendar year 2 years prior to the applicable program year and a 12-month baseline period that runs on the calendar year 4 years prior to the applicable program year for the FY 2019 program year and subsequent years.

We are not proposing any changes to these policies in this proposed rule.

f. Summary of Previously Adopted Baseline and Performance Periods for the FY 2023 Through FY 2026 Program Years

These tables summarize the baseline and performance periods that we have previously adopted.

Baseline and Performance Periods for the FY 2023 Program Year		
Domain	**Baseline Period**	**Performance Period**
Person and Community Engagement ● HCAHPS	● January 1, 2019 – December 31, 2019	● January 1, 2021 – December 31, 2021
Clinical Outcomes ● Mortality (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort) ● COMP-HIP-KNEE	● July 1, 2013 – June 30, 2016 ● April 1, 2013 – March 31, 2016	● July 1, 2018 – June 30, 2021 ● April 1, 2018 – March 31, 2021
Safety ● NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia) ● CMS PSI 90	● January 1, 2019 – December 31, 2019 ● October 1, 2015 – June 30, 2017	● January 1, 2021 – December 31, 2021 ● July 1, 2019 – June 30, 2021

Baseline and Performance Periods for the FY 2023 Program Year		
Domain	**Baseline Period**	**Performance Period**
Efficiency and Cost Reduction ● MSPB	● January 1, 2019 – December 31, 2019	● January 1, 2021 – December 31, 2021

Baseline and Performance Periods for the FY 2024 Program Year		
Domain	**Baseline Period**	**Performance Period**
Person and Community Engagement ● HCAHPS	● January 1, 2020 – December 31, 2020	● January 1, 2022 – December 31, 2022
Clinical Outcomes ● Mortality (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort) ● COMP-HIP-KNEE	● July 1, 2014 – June 30, 2017 ● April 1, 2014 – March 31, 2017	● July 1, 2019 – June 30, 2022 ● April 1, 2019 – March 31, 2022
Safety ● NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia) ● CMS PSI 90	● January 1, 2020 – December 31, 2020 ● July 1, 2016 – June 30, 2018	● January 1, 2022 – December 31, 2022 ● July 1, 2020 – June 30, 2022
Efficiency and Cost Reduction ● MSPB	● January 1, 2020 – December 31, 2020	● January 1, 2022 – December 31, 2022

Baseline and Performance Periods for the FY 2025 Program Year		
Domain	**Baseline Period**	**Performance Period**
Person and Community Engagement ● HCAHPS	● January 1, 2021 – December 31, 2021	● January 1, 2023 – December 31, 2023

Baseline and Performance Periods for the FY 2025 Program Year		
Domain	**Baseline Period**	**Performance Period**
Clinical Outcomes ● Mortality (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort) ● COMP-HIP-KNEE	● July 1, 2015 – June 30, 2018 ● April 1, 2015 – March 31, 2018	● July 1, 2020 – June 30, 2023 ● April 1, 2020 – March 31, 2023
Safety ● NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia) ● CMS PSI 90	● January 1, 2021 – December 31, 2021 ● July 1, 2017 – June 30, 2019	● January 1, 2023 – December 31, 2023 ● July 1, 2021 – June 30, 2023
Efficiency and Cost Reduction ● MSPB	● January 1, 2021 – December 31, 2021	● January 1, 2023 – December 31, 2023

Baseline and Performance Periods for the FY 2026 Program Year		
Domain	**Baseline Period**	**Performance Period**
Person and Community Engagement ● HCAHPS	● January 1, 2022 – December 31, 2022	● January 1, 2024 – December 31, 2024
Clinical Outcomes ● Mortality (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort) ● COMP-HIP-KNEE	● July 1, 2016 – June 30, 2019 ● April 1, 2016 – March 31, 2019	● July 1, 2021 – June 30, 2024 ● April 1, 2021 – March 31, 2024

Baseline and Performance Periods for the FY 2026 Program Year		
Domain	**Baseline Period**	**Performance Period**
Safety ● NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia) ● CMS PSI 90	● January 1, 2022 – December 31, 2022 ● July 1, 2018 – June 30, 2020	● January 1, 2024 – December 31, 2024 ● July 1, 2022 – June 30, 2024
Efficiency and Cost Reduction ● MSPB	● January 1, 2022 – December 31, 2022	● January 1, 2024 – December 31, 2024

4. Performance Standards for the Hospital VBP Program

a. Background

Section 1886(o)(3)(A) of the Act requires the Secretary to establish performance standards for the measures selected under the Hospital VBP Program for a performance period for the applicable fiscal year. The performance standards must include levels of achievement and improvement, as required by section 1886(o)(3)(B) of the Act, and must be established no later than 60 days before the beginning of the performance period for the fiscal year involved, as required by section 1886(o)(3)(C) of the Act. We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) for further discussion of achievement and improvement standards under the Hospital VBP Program.

In addition, when establishing the performance standards, section 1886(o)(3)(D) of the Act requires the Secretary to consider appropriate factors, such as: (1) Practical experience with the measures involved, including whether a significant proportion of hospitals failed to meet the performance standard during previous performance periods; (2) historical performance standards; (3) improvement rates; and (4) the opportunity for continued improvement.

We refer readers to the FY 2013, FY 2014, and FY 2015 IPPS/LTCH PPS final rules (77 FR 53599 through 53605; 78 FR 50694 through 50699; and 79 FR 50077 through 50081, respectively) for a more detailed discussion of the general scoring methodology used in the Hospital VBP Program. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42396) for previously established performance standards for the FY 2022 program year.

We note that the performance standards for all of the following measures are calculated with lower values representing better performance:

- CDC NHSN HAI measures (CLABSI, CAUTI, CDI, MRSA Bacteremia, and Colon and Abdominal Hysterectomy SSI).
- CMS PSI 90 measure.
- COMP–HIP–KNEE measure.
- MSPB measure.

This distinction is made in contrast to other measures—HCAHPS and the mortality measures, which use survival rates rather than mortality rates—for which higher values indicate better performance. As discussed further in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50684), the performance standards for the Colon and Abdominal Hysterectomy SSI measure are computed separately for each procedure stratum, and we first award achievement and improvement points to each stratum separately, and then compute a weighted average of the points awarded to each stratum by predicted infections.

b. Previously Established and Estimated Performance Standards for the FY 2023 Program Year

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38264 through 38265), we established performance standards for the FY 2023 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and for the Efficiency and Cost Reduction domain measure (MSPB). In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41471 through 41472), we established, for the FY 2023 program year, the performance standards for the Safety domain measure, CMS PSI 90. We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time.

In accordance with our methodology for calculating performance standards discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) and codified at 42 CFR 412.160, we are estimating additional performance standards for the FY 2023 program year. We note that the numerical values for the performance standards for the Safety and Person and Community Engagement domains for the FY 2023 program year in these tables are estimates based on the most recently available data, and we intend to update the numerical values in the FY 2021 IPPS/LTCH PPS final rule.

The previously established and estimated performance standards for the measures in the FY 2023 program year are set out in this table.

Previously Established and Estimated Performance Standards for the FY 2023 Program Year		
Measure Short Name	**Achievement Threshold**	**Benchmark**
Safety Domain♦		
CMS PSI 90*#	0.972658	0.760882
CAUTI*	0.676	0
CLABSI*	0.596	0
CDI*	0.544	0.01
MRSA Bacteremia*	0.727	0
Colon and Abdominal Hysterectomy SSI*	0.734 0.732	0 0
Clinical Outcomes Domain		
MORT-30-AMI#	0.866548	0.885499
MORT-30-HF#	0.881939	0.906798
MORT-30-PN (updated cohort) #	0.840138	0.871741
MORT-30-COPD#	0.919769	0.936349
MORT-30-CABG#	0.968747	0.979620
COMP-HIP-KNEE*#	0.027428	0.019779
Efficiency and Cost Reduction Domain		
MSPB*#	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

♦ The estimated performance standards displayed in this table for the CDC NHSN measures (CAUTI, CLABSI, CDI, MRSA Bacteremia, and Colon and Abdominal Hysterectomy SSI) were calculated using one quarter (Q4) CY 2018 data and three quarters (Q1, Q2, and Q3) CY 2019 data. We will update this table's performance standards using four quarters of CY 2019 data in the FY 2021 IPPS/LTCH PPS final rule.

* Lower values represent better performance.

Previously established performance standards.

The eight dimensions of the HCAHPS measure are calculated to generate the HCAHPS Base Score. For each of the eight dimensions, Achievement Points (0–10 points) and Improvement Points (0–9 points) are calculated, the larger of which is then summed across the eight dimensions to create the HCAHPS Base Score (0–80 points). Each of the eight dimensions is of equal weight; therefore, the HCAHPS Base Score ranges from 0 to 80 points. HCAHPS Consistency Points are then calculated, which range from 0 to 20 points. The Consistency Points take into consideration the scores of all eight Person and Community Engagement dimensions. The final element of the scoring formula is the summation of the HCAHPS Base Score and the HCAHPS Consistency Points, which results in the Person and Community Engagement Domain score that ranges from 0 to 100 points.

Estimated Performance Standards for the FY 2023 Program Year: Person and Community Engagement Domain±			
HCAHPS Survey Dimension	Floor (minimum)	Achievement Threshold (50th percentile)	Benchmark (mean of top decile)
Communication with Nurses	56.28	79.33	87.72
Communication with Doctors	62.46	79.78	87.93
Responsiveness of Hospital Staff	37.39	65.50	81.23
Communication about Medicines	44.66	63.50	74.37
Hospital Cleanliness & Quietness	45.16	65.61	79.50
Discharge Information	65.89	87.15	92.09
Care Transition	22.46	51.82	63.58
Overall Rating of Hospital	41.15	71.45	85.34

± The estimated performance standards displayed in this table were calculated using one quarter (Q4) CY 2018 data and three quarters (Q1, Q2, and Q3) CY 2019 data. We will update this table's performance standards using four quarters of CY 2019 data in the FY 2021 IPPS/LTCH PPS final rule.

c. Previously Established Performance Standards for Certain Measures for the FY 2024 Program Year

We have adopted certain measures for the Safety domain, Clinical Outcomes domain, and Efficiency and Cost Reduction domain for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41472), we established performance standards for the FY 2024 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain measure (MSPB). In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42395 through 42398), we established, for the FY 2024 program year, the performance standards for the Safety domain measure, CMS PSI 90. We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The previously established performance standards for these measures are set out in this table.

Previously Established Performance Standards for the FY 2024 Program Year		
Measure Short Name	Achievement Threshold	Benchmark
Safety Domain		
CMS PSI 90*	0.968841	0.754176
Clinical Outcomes Domain		
MORT-30-AMI	0.869247	0.887868
MORT-30-HF	0.882308	0.907733
MORT-30-PN (updated cohort)	0.840281	0.872976
MORT-30-COPD	0.916491	0.934002
MORT-30-CABG	0.969499	0.980319
COMP-HIP-KNEE*	0.025396	0.018159
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

d. Previously Established and Newly Established Performance Standards for Certain Measures for the FY 2025 Program Year

We have adopted certain measures for the Safety domain, Clinical Outcomes domain, and the Efficiency and Cost Reduction domain for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42398 through 42399), we established performance standards for the FY 2025 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain

measure (MSPB). We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time.

In accordance with our methodology for calculating performance standards discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513), and codified at 42 CFR 412.160, we are establishing performance standards for the CMS PSI 90 measure for the FY 2025 program year. The previously established and newly established performance standards for these measures are set out in this table.

Previously Established and Newly Established Performance Standards for the FY 2025 Program Year		
Measure Short Name	**Achievement Threshold**	**Benchmark**
Safety Domain		
CMS PSI 90*	0.964854	0.753807
Clinical Outcomes Domain		
MORT-30-AMI#	0.872624	0.889994
MORT-30-HF#	0.883990	0.910344
MORT-30-PN (updated cohort) #	0.841475	0.874425
MORT-30-COPD#	0.915127	0.932236
MORT-30-CABG#	0.970100	0.979775
COMP-HIP-KNEE*#	0.025332	0.017946
Efficiency and Cost Reduction Domain		
MSPB*#	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

Previously established performance standards.

e. Newly Established Performance Standards for Certain Measures for the FY 2026 Program Year

As previously discussed, we have adopted certain measures for the Clinical Outcomes domain (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain (MSPB) for future program years in order to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In accordance with our methodology for calculating performance standards discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513), and our performance standards definitions codified at 42 CFR 412.160, we are establishing the following performance standards for the FY 2026 program year for the Clinical Outcomes domain and the Efficiency and Cost Reduction domain. We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The newly established performance standards for these measures are set out in this table.

Newly Established Performance Standards for the FY 2026 Program Year		
Measure Short Name	Achievement Threshold	Benchmark
Clinical Outcomes Domain		
MORT-30-AMI	0.874426	0.890687
MORT-30-HF	0.885949	0.912874
MORT-30-PN (updated cohort)	0.843369	0.877097
MORT-30-COPD	0.914691	0.932157
MORT-30-CABG	0.970568	0.980473
COMP-HIP-KNEE*	0.024019	0.016873
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

5. Scoring Methodology and Data Requirements

a. Domain Weighting for the FY 2022 Program Year and Subsequent Years for Hospitals That Receive a Score on All Domains

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38266), we adopted a policy to retain the equal weight of 25 percent for each of the four domains in the Hospital VBP Program for the FY 2020 program year and subsequent years for hospitals that receive a score in all domains. We are not proposing any changes to these domain weights in this proposed rule.

b. Domain Weighting for the FY 2022 Program Year and Subsequent Years for Hospitals Receiving Scores on Fewer Than Four Domains

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50084 through 50085), for the FY 2017 program year and subsequent years, we adopted a policy that hospitals must receive domain scores on at least three of four quality domains in order to receive a TPS, and hospitals with sufficient data on only three domains will have their TPSs proportionately reweighted. We are not proposing any changes to these domain weights in this proposed rule.

c. Minimum Numbers of Measures for Hospital VBP Program Domains

Based on our previously finalized policies (82 FR 38266), for a hospital to receive domain scores:

- A hospital must report a minimum number of 100 completed HCAHPS surveys for a hospital to receive a Person and Community Engagement domain score.
- A hospital must receive a minimum of two measure scores within the Clinical Outcomes domain to receive a Clinical Outcomes domain score.
- A hospital must receive a minimum of two measure scores within the Safety domain to receive a Safety domain score.
- A hospital must receive a minimum of one measure score within the Efficiency and Cost Reduction domain to receive an Efficiency and Cost Reduction domain score.

We are not proposing any changes to these policies in this proposed rule.

d. Minimum Numbers of Cases for Hospital VBP Program Measures

(1) Background

Section 1886(o)(1)(C)(ii)(IV) of the Act requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for the fiscal year. For additional discussion of the previously finalized minimum numbers of cases for measures under the Hospital VBP Program, we refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26527 through 26531); the CY 2012 OPPS/ASC final rule (76 FR 74532 through 74534); the FY 2013 IPPS/LTCH PPS final rule (77 FR 53608 through 53610); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50085 through 50086); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49570); the FY 2017 IPPS/LTCH PPS final rule (81 FR 57011); the FY 2018 IPPS/LTCH PPS final rule (82 FR 38266 through 38267); the FY 2019 IPPS/LTCH PPS final rule (83 FR 41465 through 41466); and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42399 through 42400). We are not proposing any changes to these policies in this proposed rule.

(2) Summary of Previously Adopted Minimum Number of Cases

The previously adopted minimum numbers of cases for these measures are set forth in this table.

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Previously Adopted Minimum Case Number Requirements for the FY 2023 Program Year and Subsequent Years	
Measure Short Name	**Minimum Number of Cases**
Person and Community Engagement Domain	
HCAHPS	Hospitals must report a minimum number of 100 completed HCAHPS surveys.
Clinical Outcomes Domain	
MORT-30-AMI	Hospitals must report a minimum number of 25 cases.
MORT-30-HF	Hospitals must report a minimum number of 25 cases.
MORT-30-PN (updated cohort)	Hospitals must report a minimum number of 25 cases.
MORT-30-COPD	Hospitals must report a minimum number of 25 cases.
MORT-30-CABG	Hospitals must report a minimum number of 25 cases.
COMP-HIP-KNEE	Hospitals must report a minimum number of 25 cases.
Safety Domain	
CAUTI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CLABSI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
Colon and Abdominal Hysterectomy SSI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
MRSA Bacteremia	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CDI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CMS PSI 90	Hospitals must report a minimum of three eligible cases on any one underlying indicator.
Efficiency and Cost Reduction Domain	
MSPB	Hospitals must report a minimum number of 25 cases.

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e. Summary of Previously Adopted Administrative Policies for NHSN Healthcare-Associated Infection (HAI) Measure Data

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42400 through 42402), we finalized our proposal for the Hospital VBP Program to use the same data to calculate the CDC NHSN HAI measures that the HAC Reduction Program uses for purposes of calculating the measures under that program, beginning on January 1, 2020 for CY 2020 data collection, which would apply to the Hospital VBP Program starting with data for the FY 2022 program year performance period. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42402), we also finalized our proposal for the Hospital VBP Program to use the same processes adopted by the HAC Reduction Program for hospitals to review and correct data for the CDC NHSN HAI measures and to rely on HAC Reduction Program validation to ensure the accuracy of CDC NHSN HAI measure data used in the Hospital VBP Program. We are not proposing any changes to these policies in this proposed rule.

We also refer readers to section IV.M. of the preamble of this proposed rule for additional information about HAC Reduction Program refinements to validation policies for the CDC NHSN HAI measures.

M. Hospital-Acquired Condition (HAC) Reduction Program: Proposed Updates and Changes (42 CFR 412.170)

1. Regulatory Background

We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50708) for a general overview of the HAC Reduction Program and to the same final rule (78 FR 50708 through 50709) for a detailed discussion of the statutory basis for the Program. For additional descriptions of our previously finalized policies for the HAC Reduction Program, we also refer readers to the following final rules:

- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50729).
- The FY 2015 IPPS/LTCH PPS final rule (79 FR 50087 through 50104).
- The FY 2016 IPPS/LTCH PPS final rule (80 FR 49570 through 49581).
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57011 through 57026).
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38269 through 38278).
- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41472 through 41492).
- The FY 2020 IPPS/LTCH PPS final rule (84 FR 42402 through 42411).

These rules describe the general framework for the HAC Reduction Program's implementation, including: (1) The relevant definitions applicable to the program; (2) the payment adjustment under the program; (3) the measure selection process and conditions for the program, including a risk adjustment and scoring methodology; (4) performance scoring; (5) data collection; (6) validation; (7) measure removal factors policy; (8) the process for making hospital-specific performance information available to the public, including the opportunity for a hospital to review the information and submit corrections; (9) the extraordinary circumstance exception policy; and (10) limitation of administrative and judicial review. We remind readers that data collection and validation policies (items (5) and (6)) were finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41472 through 41492) and further clarified in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42402 through 42411).

We have also codified certain requirements of the HAC Reduction Program at 42 CFR 412.170 through 412.172.

2. Summary of Proposed Policies for the HAC Reduction Program

In section IV.M.4. of the preamble of this proposed rule, we are proposing the automatic adoption of applicable periods beginning with the FY 2023 program year and all subsequent program years, unless otherwise specified by the Secretary. In section IV.M.6. of the preamble of this proposed rule, we are proposing refinements to the HAC Reduction Program validation procedures. Finally, in section IV.M.7. of the preamble of this proposed rule, we are proposing to update the definition of *applicable period* at 42 CFR 412.170 to align with this proposal.

3. Measures for FY 2021 and Subsequent Years

a. Current Measures

The HAC Reduction Program has adopted six measures to date. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we finalized the use of five CDC NHSN HAI measures: (1) CAUTI; (2) CDI; (3) CLABSI; (4) Colon and Abdominal Hysterectomy SSI; and (5) MRSA Bacteremia. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57014), we also finalized the use of the CMS PSI 90 measure. These previously finalized measures, with their full measure names, are shown in this table.

HAC Reduction Program Measures for FY 2021

Short Name	Measure Name	NQF #
CMS PSI 90	CMS Patient Safety and Adverse Events Composite (PSI)	0531
CAUTI	CDC NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CDI	CDC NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure	1717
CLABSI	CDC NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753
MRSA Bacteremia	CDC NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure	1716

Technical specifications for the CMS PSI 90 measure can be found on the QualityNet website. Technical specifications for the CDC NHSN HAI measures can be found at CDC's NHSN website at: *http://www.cdc.gov/nhsn/acute-care-hospital/index.html.* Both websites provide measure updates and other information necessary to guide hospitals participating in the collection of HAC Reduction Program data.

In this proposed rule, we are not proposing to adopt or remove any measures.

b. Measure Removal Factors Policy

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41472 through 41474) for more information about how the HAC Reduction Program supports CMS' goal of bringing quality measurement, transparency, and improvement together with value-based purchasing to the hospital inpatient care setting through the Meaningful Measures Initiative. We also refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42404 through 42406) for information about our measure removal and retention factors for the HAC Reduction Program. In this proposed rule, we are not proposing any removal and retention factor policy changes.

4. Applicable Period for the HAC Reduction FY 2023 Program Year and Subsequent Years

As we stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we believe that using 24-month data collection periods for the CMS PSI 90 and CDC NHSN HAI measures for the HAC Reduction Program provides hospitals and the general public the most current data available. The 24-month data period also allows time to complete the complex calculation process for these measures, to perform comprehensive quality assurance to enhance the accuracy of measure results, and to disseminate confidential reports on hospital-level results to individual hospitals. Though we had truncated the applicable period to shorter than a 24-month data collection period for the CMS PSI 90 to accommodate the transition to the ICD–10 classification system for FY 2018 and 2019,[463] we returned to using the full 24-month data collection period as soon as the ICD–10 transition was complete. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38271), for FY 2020, we finalized the applicable period for the CMS PSI 90 as the 24-month period from July 1, 2016 through June 30, 2018. Additionally, we finalized the applicable period for the CDC NHSN HAI measures (CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI), as the 24-month period from January 1, 2017 through December 31, 2018. We have finalized the 24-month applicable periods for FYs 2021 and 2022 [464] consistent with these applicable periods and with the definition specified at § 412.170.

We continue to believe that the 24-month period is the appropriate data collection period for both the CMS PSI 90 and CDC NHSN HAI measures. In order to provide greater certainty around future applicable periods for the HAC Reduction Program, we are proposing the automatic adoption of applicable periods for the FY 2023 program year and all subsequent program years for the HAC Reduction Program. Beginning in FY 2023, the applicable period for both the CMS PSI 90 and CDC NHSN HAI measures will be the 24-month period beginning 1 year advanced from the previous program year's start of the applicable period. That is, for FY 2023, the applicable period for the CMS PSI 90 would be the 24-month period from July 1, 2019 through June 30, 2021, and the applicable period for CDC NHSN HAI measures would be the 24-month period from January 1, 2020 through December 31, 2022, which is advanced 1 year from the applicable period for the FY 2022 HAC Reduction Program. All subsequent years would advance this 24-month period by 1 year unless otherwise specified by the Secretary, which we would convey through notice and comment rulemaking. We believe that the automatic adoption of the applicable period each year would streamline the process and provide additional clarity and consistency to the Program.

5. HAC Reduction Program Scoring Methodology and Scoring Review and Corrections Period

In FY 2019 IPPS/LTCH PPS final rule (83 FR 41484 through 41489), we adopted the Equal Measure Weights approach to scoring and clarified the ''Scoring Calculations Review and Correction Period'' (83 FR 41484). Hospitals must register for a QualityNet Secure Portal account in order to access their annual hospital-specific reports. We will continue using this scoring methodology and the ''Scoring Calculations Review and Correction Period'' process in FY 2021 and for subsequent years.

6. Validation of HAC Reduction Program Data

a. Background

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41478 through 41484), we adopted processes to validate the CDC NHSN HAI measure data used in the HAC Reduction Program, because the Hospital IQR Program finalized its proposals to remove CDC NHSN HAI measures from its program. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42406 through 42410), we provided additional clarification to the validation selection and scoring methodology. We also refer readers to the QualityNet website for more information regarding chart-abstracted data validation of measures.

In the FY 2019 IPPS/LTCH PPS final rule, we finalized our policy that the HAC Reduction Program will begin validation with Q3 2020 discharges, which must be reported by February 2021 using the following validation schedule.

[463] FY 2017 IPPS/LTCH PPS final rule (81 FR 57020).

[464] FY 2019 IPPS/LTCH PPS final rule (83 FR 41489); FY 2020 IPPS/LTCH PPS final rule (84 FR 42410).

Finalized Validation Period for the HAC Reduction Program in FY 2023 [*Dates are subject to change]					
Discharge Quarters by Fiscal Year (FY)	**Current CDC NHSN HAI Submission Deadline***	**Current CDC NHSN HAI Validation Templates***	**Estimated CDAC[1] Record Request**	**Estimated Date Records Due to CDAC**	**Estimated Validation Completion**
Q1 2020	08/15/2020				
Q2 2020	11/15/2020				
Q3 2020^	**02/15/2021**	**02/01/2021**	**02/28/2021**	**03/30/2021**	**06/15/2021**
Q4 2020^	**05/15/2021**	**05/01/2021**	**05/30/2021**	**06/29/2021**	**09/15/2021**
Q1 2021^	**08/15/2021**	**08/01/2021**	**08/30/2021**	**09/29/2021**	**12/15/2021**
Q2 2021^	**11/15/2021**	**11/01/2021**	**11/29/2021**	**12/29/2021**	**03/15/2022**

Bolded rows with dates in each column, denoted with the ^ symbol next to the date in the Discharge Quarter by Fiscal Year (FY) column, indicate the validation cycle for the FY.

We also adopted a policy that any nonsubstantive updates to the procedures for validation of chart-abstracted measures will be provided on the QualityNet website.

We are proposing several changes to the process for validation of HAC Reduction Program measure data to align this program with the proposed changes to the Hospital IQR Program measure validation process. Specifically, we intend to align the hospital selection and submission quarters beginning with FY 2024 Hospital IQR and HAC Reduction Programs validation so that we only require one pool of hospitals to submit data for validation. We believe that this would reduce burden and streamline processes. Our specific proposals to update the HAC Reduction Program validation process are described later in this section. For more information on the proposed updates to the Hospital IQR measure validation process, see section VIII.A. of the preamble of this proposed rule.

b. Proposed Updates to Process for Validation of HAC Reduction Program Measure Data

1. Aligning Submission Quarters to Hospital IQR Submissions

To support the transition to an aligned validation program for the HAC Reduction Program and the Hospital IQR Program, we are proposing to change the quarters of data used for HAC Reduction Program measure validation. Under the existing validation structure, hospitals selected for validation for the FY 2023 program year would be required to submit HAC Reduction Program measure data from the third and fourth quarters of 2020 and the first and second quarters of 2021 (as depicted in the table in section IV.M.6.a. of the preamble of this proposed rule).

In order to align the quarters used for HAC Reduction Program and Hospital IQR validation, we are proposing to only use measure data from the third and fourth quarters of 2020 for the FY 2023 program year (illustrated in this table). We would use measure data from only these quarters for both the random and targeted validation pools.

Proposal to Align Quarters Used for Validation for FY 2023	
Fiscal Year 2023	**Quarter**
HAC Reduction Program Data	3Q20
	4Q20

For the FY 2024 program year and subsequent years, we are proposing to use measure data from all of CY 2021 for both the HAC Reduction Program and the Hospital IQR Program. Under this proposal, the data submission deadlines for chart-abstracted measures would be in the middle of the month, the fifth month following the end of the reporting quarter.

Proposal to Align Quarters Used for Validation for FY 2024 and Subsequent Years	
Fiscal Year 2024	**Quarter**
HAC Reduction Program Data	1Q21
	2Q21
	3Q21
	4Q21

[465] The CMS Clinical Data Abstraction Center (CDAC) performs the validation.

We invite public comment on our proposal to align submission quarters and deadlines with the Hospital IQR Program.

2. Aligning Hospital Selection

Currently, a total of up to 600 hospitals may be selected for validation under the HAC Reduction Program. This is achieved by the HAC Reduction Program taking an annual sample of up to 400 randomly selected hospitals and selecting up to 200 hospitals using targeting criteria. We are not proposing any changes to the hospital selection for validation for the FY 2023 program year. However, we are proposing to update the policies to reduce the total validation pool from up to 600 hospitals to up to 400 hospitals, effective with validation for the FY 2024 program year. This would align with proposals being made by the Hospital IQR Program in section VIII.A. of the preamble of this proposed rule. To achieve this reduction, we propose reducing the randomly selected hospital pool from up to 400 hospitals to up to 200 hospitals for validation for the FY 2024 program year and subsequent years. We note that these would be the same hospitals as those selected for validation under the Hospital IQR Program to the extent that the IQR program has measures for those hospitals; therefore, we would be selecting a total of up to 400 hospitals across both the HAC Reduction Program and the Hospital IQR Program. This would reduce the total number of hospitals selected for validation across both programs by approximately one third each year. We believe reducing the total number of hospitals randomly selected for chart-abstracted measure validation to ''up to 200'' would maintain a sufficient sample size for a statistically meaningful estimate of hospitals' reporting accuracy and help streamline the process for both programs. We invite public comment on our proposal to align hospital selection with the Hospital IQR Program for FY 2024 payment determination and subsequent years.

3. Requiring the Use of Digital Submissions for Medical Records Requests

We are proposing to require hospitals to submit digital files when submitting medical records for validation of HAC Reduction Program measures, for the FY 2024 program year and subsequent years. Currently, hospitals may choose to submit paper copies of medical records for chart-abstracted measure validation or they may submit patient charts for validation by securely transmitting electronic versions of medical information (83 FR 41478 through 41484). Currently, submission via secure transmission can either entail downloading or copying the digital image of the patient chart onto CD, DVD, or flash drive, or submission of PDFs using a CMS-approved secured file transfer system.

In this proposed rule, in alignment with proposals made for the Hospital IQR Program in section VIII.A. of the preamble of this proposed rule, we are proposing to discontinue the option of sending CD, DVD, or flash drives containing digital images of patient charts, beginning with Q1 2021 for FY 2024 program year validation. Under this proposal, hospitals would be required to submit PDF copies of medical records using direct electronic files submission via a CMS-approved secure file transmission process. We would continue to reimburse hospitals at $3.00 per chart, consistent with current reimbursement for electronic submissions of charts.

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 (78 FR 50834). Additionally, we monitor the medical records submissions to the CMS Clinical Data Abstraction Center (CDAC) contractor, and have found almost two-thirds of providers use the option to submit PDF copies of medical records as electronic files. We note that paper submissions can be reimbursed at a higher rate than for electronic submissions, especially for longer records because paper submissions are reimbursed on a per page basis, while electronic submissions are reimbursed using a flat rate for each submission. In our assessment based on the monitoring we believe the electronic submissions can be a more effective and efficient process for the hospitals selected for validation. Requiring electronic file submissions reduces the burden of not only coordinating numerous paper-based pages of medical records and making photocopies, but also shipping it to the CDAC. Therefore, we believe it is appropriate to require that hospitals use electronic submissions via a CMS-approved secure file transmission process. We invite public comment on this proposal in section VIII.A of the preamble of this proposed rule.

7. Regulatory Updates (42 CFR 412.170)

We are proposing to amend the definition of *applicable period* at 42 CFR 412.170 to align with our proposed automatic adoption of applicable periods in future program years. Section 412.170 currently defines *applicable period* as the 2-year period specified by the Secretary from which data are collected in order to calculate the total hospital-acquired condition score under the HAC Reduction Program. The proposed amendment to the definition would add language to specify: (1) The applicable period of the CMS PSI 90 and CDC NHSN HAI measures for the FY 2023 HAC Reduction Program; and (2) beginning with the FY 2023 program year, the applicable period will be advanced by 1 year from the prior from the prior fiscal year's applicable period. This addition to the definition at 42 CFR 412.170 makes it so applicable periods for future program years do not need to be defined during rulemaking.

N. Payments for Indirect and Direct Graduate Medical Education Costs (§§ 412.105 and 413.75 Through 413.83)

1. Overview of Medicare Direct GME and IME

The Medicare program makes payments to teaching hospitals to account for two types of costs, the direct costs (direct GME) and the indirect costs (IME) of a hospital's graduate medical education program. Direct GME payments represent the direct costs of training residents (for example, resident salaries, fringe benefits, and teaching physician costs associated with an approved GME program) and generally are calculated by determining the product of the Medicare patient load (that is, the percentage of the hospital's Medicare inpatient days), the hospital's per resident payment amount, and the weighted number of FTE residents training at the hospital during the cost reporting period.

The IME adjustment is made to teaching hospitals for the additional indirect patient care costs attributable to teaching activities. For example, teaching hospitals typically offer more technologically advanced treatments to their patients, and therefore, patients who are sicker and need more sophisticated treatment are more likely to go to teaching hospitals. Furthermore, there are additional costs related to the presence of inefficiencies associated with teaching residents resulting from the additional tests or procedures ordered by residents and the demands put on physicians who supervise, and staff who support, the residents. IME payments are made for each inpatient

discharge as a percentage add-on adjustment to the Hospital Inpatient Prospective Payment System (IPPS) payment, and are calculated based on the hospital's ratio of FTE residents to available beds as defined at § 412.105(b). The statutory formula for calculating the IME adjustment is: $c \times [(1 + r)^{.405} - 1]$, where ''r'' represents the hospital's ratio of FTE residents to beds, and ''c'' represents an IME multiplier, which is set by the Congress.

The amount of IME payment a hospital receives for a particular discharge is dependent upon the number of FTE residents the hospital trains, the hospital's number of available beds, the current level of the statutory IME multiplier, and the per discharge IPPS payment. Sections 1886(d)(5)(B)(v) and 1886(h)(4)(F) of the Act established hospital specific limits (that is, caps) on the number of allopathic and osteopathic FTE residents that hospitals may count for purposes of calculating indirect and direct GME payments, respectively.

2. Existing Regulations Related to Residency Program or Teaching Hospital Closure

The regulations at 42 CFR 413.79(h) for direct GME, and 42 CFR 412.105(f)(1)(ix) for IME provide for a hospital that is closing or closing its residency program(s) to volunteer to temporarily transfer a portion of its hospital-specific direct GME and IME FTE resident caps to other hospitals that are willing to accept and train the displaced resident(s) for the duration of the resident's training program. CMS first implemented regulations regarding residents displaced by teaching hospital closure in the July 30, 1999 IPPS final rule (64 FR 41522). We made the change to allow a receiving hospital to receive temporary IME and direct GME cap adjustments in limited circumstances due to hospital closure for assuming the training of displaced residents because of a reluctance on the part of receiving hospitals to assume these displaced residents without attending increases to their IME and direct GME FTE resident caps to ensure receipt of Medicare funding. We define ''closure of a hospital'' at 42 CFR 413.79(h)(1)(i) as a situation in which ''the hospital terminates its Medicare agreement under the provisions of § 489.52 of this chapter.'' At 42 CFR 413.79(h)(2), our regulations state that a hospital may receive a temporary adjustment to its FTE cap to reflect residents added because of another hospital's closure if the hospital meets the following: The hospital is training additional residents from a hospital that closed on or after July 1, 1996, and no later than 60 days after the hospital begins to train the residents, the hospital submits a request to its contractor for a temporary adjustment to its FTE cap, documents that the hospital is eligible for this temporary adjustment by identifying the residents who have come from the closed hospital and have caused the hospital to exceed its cap, and specifies the length of time the adjustment is needed.

Subsequently, in the August 1, 2001 IPPS final rule (66 FR 39899), we further added to the regulations at 42 CFR 413.79(h) to also allow a receiving hospital to receive temporary IME and direct GME cap adjustments due to closure of a residency program (although the hospital itself would remain open) for assuming the training of displaced residents due to similar reluctance on the part of receiving hospitals to accept these displaced residents without attending increases to their IME and direct GME FTE resident caps to ensure receipt of Medicare funding. We define ''closure of a hospital residency training program'' at 42 CFR 413.79(h)(1)(ii) to mean the hospital ceases to offer training for residents in a particular approved medical residency training program. However, because the hospital with the closing program itself remains open in the case of program closure, it retains its full IME and direct GME FTE resident caps. In order to prevent the situation of double payment for the same FTE resident cap slots, where the originating hospital closes a program and fills its vacated slots with residents from a different specialty, while the receiving hospital also receives payment for training the displaced resident, we stated in regulation that a receiving hospital could only receive the temporary FTE resident cap adjustment if the originating hospital with the closed program voluntarily agreed to temporarily reduce its FTE resident caps for the duration of the displaced residents' training at the receiving hospital (see 66 FR 39900 August 1, 2001). We revised the regulations at 42 CFR 413.79(h)(3) to specify the responsibilities of the closing hospital or program and the receiving hospital.

3. Proposed Policy Change Related to Medical Residents Affected by Residency Program or Teaching Hospital Closure

When teaching hospitals have closed, we receive many inquiries from concerned stakeholders about whether Medicare IME and direct GME funding could be seamlessly maintained for the medical residents that would have to find alternate training hospitals to complete their training. However, although not explicitly stated in regulations text, our current policy is that the definition of 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 both the regulations text under hospital closure and program closure, there is a requirement that the receiving hospital identifies the residents'' who have come from the closed hospital,'' or ''identifies the residents who were in training at the time of the program's closure'' (see 42 CFR 413.79(h)(2)(ii) and (h)(3)(ii)(B)). We considered the residents who were physically present at the hospital to be those residents who were ''training at the time of the program or hospital closure,'' thereby granting them the status of ''displaced residents.'' However, stakeholders have voiced their concern that by limiting 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 hospitals/programs to have their residencies continue to be funded by Medicare: (1) Residents who leave the program after the closure is publicly announced to continue training at another hospital, but before the actual closure; (2) residents assigned to and training at planned rotations at other hospitals who will be unable to return to their rotations at the closing hospital or program; and (3) individuals (such as medical students or would-be fellows) who matched into GME programs at the closing hospital or program but have not yet started training at the closing hospital or program. Other groups of residents who, under current policy, are already considered ''displaced residents'' include—(1) residents who are physically training in the hospital on the day prior to or day of program or hospital closure; and (2) residents who would have been at the closing hospital/program on the day prior to or of closure, but for the fact that they were on approved leave at that time, and will be unable to return to their training at the closing hospital/program.

We are proposing to amend the Medicare policy with regard to closing teaching hospitals and closing residency programs to address the needs of residents attempting to find alternative hospitals in which to complete their training and the incentives of originating and receiving hospitals with regard to seamless Medicare IME and direct GME funding. We are proposing

to change two aspects of the current Medicare policy. First, rather than link the Medicare temporary funding for the affected residents to the day prior to or the day of program or hospital closure, we propose that the key day would 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 would provide greater flexibility for the residents to transfer while the hospital operations or residency programs were winding down, rather than waiting until the last day of hospital or program operation. This would address the needs of the first group of residents as previously described: Residents who would leave the program after the closure was publicly announced to continue training at another hospital, but before the day of actual closure. Second, by removing the link between Medicare temporary funding for the residents, and the day prior to or the day of program or hospital closure, we propose to also allow funding to be transferred temporarily for the second and third group of residents who are not physically at the closing hospital/closing program, but had intended to train at (or return to training at, in the case of residents on rotation) the closing hospital/closing program.

Thus, we are proposing to revise our policy with regard to which residents can be considered ''displaced'' for Medicare temporary FTE resident cap transfer purposes in the situation where a hospital announces publicly that it is closing, and/or that it is closing a residency program(s). Specifically, we are proposing to add the definition of ''displaced resident'' in new 42 CFR 413.79(h)(1)(iii) to read as set out in the regulatory text of this document.

Current IME regulations at 42 CFR 412.105(f)(1)(ix) link to the direct GME regulations at 42 CFR 413.79(h), so this proposed regulation change would apply to the IME FTE cap transfers for displaced residents as well. In order to fully coordinate these IME regulations with the new proposed definition of ''displaced resident,'' we are proposing to slightly modify the regulations at 42 CFR 412.105(f)(1)(ix) to add the word ''displaced'' to describe residents added by a receiving hospital due to a hospital or program closure. In addition, we are proposing to change another detail of the policy specific to the requirements for the receiving hospital. To apply for the temporary increase in the Medicare resident cap, the receiving hospital would have to submit a letter to its Medicare Administrative Contractor within 60 days of beginning the training of the displaced residents. In the July 30, 1999 IPPS final rule (64 FR 41523), we stated that this letter must include the names and social security numbers of the displaced residents, the hospital and programs in which the residents were training previously, and the amount of the cap increase needed for each resident (based on how much the receiving hospital is in excess of its caps and the length of time for which the adjustments are needed (42 CFR 413.79(h)(2)(ii)). To reduce the amount of personally identifiable information (PII) included in these agreements, we are proposing to no longer require the full social security number for each resident. However, in order to still provide enough information for the hospitals and MACs to be able to differentiate among many residents, some which may have similar names, we are proposing to require the receiving hospital to include the names and the last four digits of each displaced resident's social security number.

We are also noting that as under current policy, the maximum number of FTE resident cap slots that could be transferred to all receiving hospitals is the number of IME and direct GME FTE resident cap slots belonging to the hospital that has the closed program, or that is closing. Therefore, if the originating hospital is training residents in excess of its caps, then being a displaced resident does not guarantee that a cap slot will be transferred along with that resident. A closure situation does not grant the Medicare program the authority to fund additional residency slots in excess of the cap amounts at the originating hospital. If there are more displaced residents than available cap slots, the slots may be apportioned, according to the closing hospital's discretion. The decision to transfer a cap slot if one is available is voluntary and made at the sole discretion of the originating hospital (42 CFR 413.79(h)(3)(ii)). However, if the originating hospital decides to do so, then it is the originating hospital's and/or sponsor's responsibility to determine how much of an available cap slot goes with a particular resident (if any). (Also note that only to the extent a receiving hospital would exceed its FTE cap by training displaced residents would it be eligible for the temporary adjustment (66 FR 39899, § 413.79(h)(3)(i)(B)). A receiving hospital is paid for the displaced resident using its own direct GME and IME factors, that is, the same rates as those used for residents in its own programs (see 66 FR 39901 August 1, 2001).

O. Rural Community Hospital Demonstration Program

1. Introduction

The Rural Community Hospital Demonstration was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148). Subsequently, section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted December 13, 2016, amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act, as further discussed in this proposed rule). Section 15003 also required that, no later than 120 days after enactment of Public Law 114–255, the Secretary had to issue a solicitation for applications to select additional hospitals to participate in the demonstration program for the second 5 years of the 10-year extension period, so long as the maximum number of 30 hospitals stipulated by Public Law 114–148 was not exceeded. In this proposed rule, we are providing a description of the provisions of section 15003 of Public Law 114–255, our final policies for implementation, and the finalized budget neutrality methodology for the extension period authorized by section 15003 of Public Law 114–255. We note that the periods of participation for a number of the hospitals selected prior to the extension period authorized by Public Law 114–255 will have ended by the close of FY 2021, and that the budget neutrality methodology for this upcoming fiscal year will take into account the schedule of end dates.

2. Background

Section 410A(a) of Public Law 108–173 required the Secretary to establish a demonstration program to test the feasibility and advisability of establishing rural community hospitals to furnish covered inpatient hospital services to Medicare beneficiaries. The demonstration pays rural community hospitals under a reasonable cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1) of Public Law 108–173, is a hospital that—

- Is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act;

• Has fewer than 51 beds (excluding beds in a distinct part psychiatric or rehabilitation unit) as reported in its most recent cost report;

• Provides 24-hour emergency care services; and

• Is not designated or eligible for designation as a CAH under section 1820 of the Act.

Section 410A of Public Law 108–173 required a 5-year period of performance. Subsequently, sections 3123 and 10313 of Public Law 111–148 required the Secretary to conduct the demonstration program for an additional 5-year period, to begin on the date immediately following the last day of the initial 5-year period. Public Law 111–148 required the Secretary to provide for the continued participation of rural community hospitals in the demonstration program during the 5-year extension period, in the case of a rural community hospital participating in the demonstration program as of the last day of the initial 5-year period, unless the hospital made an election to discontinue participation. In addition, Public Law 111–148 limited the number of hospitals participating to no more than 30. We refer readers to previous final rules for a summary of the selection and participation of these hospitals. Starting from December 2014 and extending through December 2016, the 21 hospitals that were still participating in the demonstration ended their scheduled periods of performance on a rolling basis, respectively, according to the end dates of the hospitals' cost report periods.

3. Provisions of the 21st Century Cures Act (Pub. L. 114–255) and Finalized Policies for Implementation

a. Statutory Provisions

As stated earlier, section 15003 of Public Law 114–255 further amended section 410A of Public Law 108–173 to require the Secretary to conduct the Rural Community Hospital Demonstration for a 10-year extension period (in place of the 5-year extension period required by Public Law 111–148), beginning on the date immediately following the last day of the initial 5-year period under section 410A(a)(5) of Public Law 108–173. Thus, the Secretary is required to conduct the demonstration for an additional 5-year period. Specifically, section 15003 of Public Law 114–255 amended section 410A(g)(4) of Public Law 108–173 to require that, for hospitals participating in the demonstration as of the last day of the initial 5-year period, the Secretary shall provide for continued participation of such rural community hospitals in the demonstration during the 10-year extension period, unless the hospital makes an election, in such form and manner as the Secretary may specify, to discontinue participation. Furthermore, section 15003 of Public Law 114–255 added subsection (g)(5) to section 410A of Public Law 108–173 to require that, during the second 5 years of the 10-year extension period, the Secretary shall apply the provisions of section 410A(g)(4) of Public Law 108–173 to rural community hospitals that are not described in subsection (g)(4) but that were participating in the demonstration as of December 30, 2014, in a similar manner as such provisions apply to hospitals described in subsection (g)(4).

In addition, section 15003 of Public Law 114–255 amended section 410A of Public Law 108–173 to add paragraph (g)(6)(A). This new paragraph required that the Secretary issue a solicitation for applications no later than 120 days after enactment of paragraph (g)(6) to select additional rural community hospitals located in any State to participate in the demonstration program for the second 5 years of the 10-year extension period, without exceeding the maximum number of hospitals (that is, 30) permitted under section 410A(g)(3) of Public Law 108–173 (as amended by Public Law 111–148). Section 410A(g)(6)(B) provided that, in determining which hospitals submitting an application pursuant to this solicitation were to be selected for participation in the demonstration, the Secretary must give priority to rural community hospitals located in one of the 20 States with the lowest population densities, as determined using the 2015 Statistical Abstract of the United States. The Secretary was also instructed to consider closures of hospitals located in rural areas in the State in which an applicant hospital is located during the 5-year period immediately preceding the date of enactment of Public Law 114–255 (December 13, 2016), as well as the population density of the State in which the rural community hospital is located.

b. Terms of Participation for the Extension Period Authorized by Public Law 114–255

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38280), we finalized our policy with regard to the effective date for the application of the reasonable cost-based payment methodology under the demonstration for those previously participating hospitals choosing to participate in the second 5-year extension period. According to our finalized policy, each previously participating hospital began the second 5 years of the 10-year extension period and payment for services provided under the cost-based payment methodology under section 410A of Public Law 108–173 (as amended by section 15003 of Public Law 114–255) on the date immediately after the period of performance ended under the first 5-year extension period.

Seventeen of the 21 hospitals that completed their periods of participation under the extension period authorized by Public Law 111–148 elected to continue in the second 5-year extension period for the full second 5-year extension period. (Of the four hospitals that did not elect to continue participating, three hospitals converted to CAH status during the time period of the second 5-year extension period). Therefore, the 5-year period of performance for each of these hospitals started on dates beginning May 1, 2015 and extending through January 1, 2017. On November 20, 2017, we announced that, as a result of the solicitation issued earlier in the year responding to the requirement in Public Law 114–255, 13 additional hospitals were selected to participate in the demonstration in addition to these 17 hospitals continuing participation from the first 5-year extension period. (Hereafter, these two groups are referred to as ''newly participating'' and ''previously participating'' hospitals, respectively.) We announced that each of these newly participating hospitals would begin its 5-year period of participation effective with the start of the first cost-reporting period on or after October 1, 2017. One of the hospitals selected from the solicitation in 2017 withdrew from the demonstration program prior to beginning participation in the demonstration on July 1, 2018. In addition, one of the previously participating hospitals closed effective January 2019, and another withdrew effective October 1, 2019. Therefore, 27 hospitals were participating in the demonstration as of this date—15 previously participating and 12 newly participating. For four of the previously participating hospitals, this 5-year period of participation will end during FY 2020; for 8 of the remaining 11 hospitals among this group, participation will end during FY 2021, with participation ending for the other three on December 31, 2021. The newly participating hospitals are all scheduled to end their participation either at the end of FY 2022 or during FY 2023.

4. Budget Neutrality

a. Statutory Budget Neutrality Requirement

Section 410A(c)(2) of Public Law 108–173 requires that, in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented. This requirement is commonly referred to as ''budget neutrality.'' Generally, when we implement a demonstration program on a budget neutral basis, the demonstration program is budget neutral on its own terms; in other words, the aggregate payments to the participating hospitals do not exceed the amount that would be paid to those same hospitals in the absence of the demonstration program. Typically, this form of budget neutrality is viable when, by changing payments or aligning incentives to improve overall efficiency, or both, a demonstration program may reduce the use of some services or eliminate the need for others, resulting in reduced expenditures for the demonstration program's participants. These reduced expenditures offset increased payments elsewhere under the demonstration program, thus ensuring that the demonstration program as a whole is budget neutral or yields savings. However, the small scale of this demonstration program, in conjunction with the payment methodology, made it extremely unlikely that this demonstration program could be held to budget neutrality under the methodology normally used to calculate it—that is, cost-based payments to participating small rural hospitals were likely to increase Medicare outlays without producing any offsetting reduction in Medicare expenditures elsewhere. In addition, a rural community hospital's participation in this demonstration program would be unlikely to yield benefits to the participants if budget neutrality were to be implemented by reducing other payments for these same hospitals. Therefore, in the 12 IPPS final rules spanning the period from FY 2005 through FY 2016, we adjusted the national inpatient PPS rates by an amount sufficient to account for the added costs of this demonstration program, thus applying budget neutrality across the payment system as a whole rather than merely across the participants in the demonstration program. (A different methodology was applied for FY 2017.) As we discussed in the FYs 2005 through 2017 IPPS/LTCH PPS final rules (69 FR 49183; 70 FR 47462; 71 FR 48100; 72 FR 47392; 73 FR 48670; 74 FR 43922, 75 FR 50343, 76 FR 51698, 77 FR 53449, 78 FR 50740, 79 FR 50145; 80 FR 49585; and 81 FR 57034, respectively), we believe that the language of the statutory budget neutrality requirements permits the agency to implement the budget neutrality provision in this manner.

b. Methodology Used in Previous Final Rules for Periods Prior to the Extension Period Authorized by the 21st Century Cures Act (Pub. L. 114–255)

We have generally incorporated two components into the budget neutrality offset amounts identified in the final IPPS rules in previous years. First, we have estimated the costs of the demonstration for the upcoming fiscal year, generally determined from historical, ''as submitted'' cost reports for the hospitals participating in that year. Update factors representing nationwide trends in cost and volume increases have been incorporated into these estimates, as specified in the methodology described in the final rule for each fiscal year. Second, as finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier, given year, differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. If the actual costs for the demonstration for the earlier fiscal year exceeded the estimated costs of the demonstration identified in the final rule for that year, this difference was added to the estimated costs of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. Conversely, if the estimated costs of the demonstration set forth in the final rule for a prior fiscal year exceeded the actual costs of the demonstration for that year, this difference was subtracted from the estimated cost of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. (We note that we have calculated this difference for FYs 2005 through 2015 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years).

c. Budget Neutrality Methodology for the Extension Period Authorized by the 21st Century Cures Act (Pub. L. 114–255)

(1) General Approach

We finalized our budget neutrality methodology for periods of participation under the second 5 years of the 10-year extension period in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38285 through 38287). Similar to previous years, we stated in this rule, as well as in the FY 2019 and FY 2020 IPPS/LTCH PPS proposed and final rules (83 FR 20444 and 41503, and 84 FR19452 and 42421, respectively) that we would incorporate an estimate of the costs of the demonstration, generally determined from historical, ''as submitted'' cost reports for the participating hospitals and appropriate update factors, into a budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year. In addition, we stated that we would continue to apply our general policy from previous years of including, as a second component to the budget neutrality offset amount, the amount by which the actual costs of the demonstration for an earlier, given year (as determined from finalized cost reports when available) differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year.

In these proposed and final rules, we described several distinct components to the budget neutrality offset amount for the specific fiscal years of the extension period authorized by Public Law 114–255.

- We included a component to our overall methodology similar to previous years, according to which an estimate of the costs of the demonstration for both previously and newly participating hospitals for the upcoming fiscal year is incorporated into a budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year. In the FY 2019 IPPS final rule (83 FR 41506), we included such an estimate of the costs of the demonstration for each of FYs 2018 and 2019 into the budget neutrality offset amount for FY 2019. In the FY 2020 IPPS final rule, we included an estimate of the costs of the demonstration for FY 2020 for 28 hospitals.
- Similar to previous years, we continued to implement the policy of determining the difference between the actual costs of the demonstration as determined from finalized cost reports for a given fiscal year and the estimated costs indicated in the corresponding year's final rule, and including that

difference as a positive or negative adjustment in the upcoming year's final rule. (For each previously participating hospital that has decided to participate in the second 5 years of the 10-year extension period, the cost-based payment methodology under the demonstration began on the date immediately following the end date of its period of performance for the first 5-year extension period. In addition, for previously participating hospitals that converted to CAH status during the time period of the second 5-year extension period, the demonstration payment methodology was applied to the date following the end date of its period of performance for the first extension period to the date of conversion). In the FY 2020 final rule, we included the difference between the amount determined for the cost of the demonstration in each of FYs 2014 and 2015 and the estimated amount included in the budget neutrality offset in the final rule for each of these respective fiscal years. For FY 2016 and subsequent years we will use finalized cost reports when available that detail the actual costs of the demonstration for each of these fiscal years and incorporate these amounts into the budget neutrality calculation.

(2) Methodology for Estimating Demonstration Costs for FY 2021

We are using a methodology similar to previous years, according to which an estimate of the costs of the demonstration for the upcoming fiscal year is incorporated into a budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year, that is, FY 2021. Noting again that four of the previously participating hospitals will end their participation during FY 2020, we are conducting this estimate for FY 2021 on the basis of the 23 hospitals that will participate during that fiscal year. The methodology for calculating this amount for FY 2021 proceeds according to the following steps:

Step 1: For each of these 23 hospitals, we identify the reasonable cost amount calculated under the reasonable cost-based methodology for covered inpatient hospital services, including swing beds, as indicated on the ''as submitted'' cost report for the most recent cost reporting period available. For each of these hospitals, these ''as submitted'' cost reports are those with cost report period end dates in CY 2018. We note that among the eight hospitals that are scheduled to end participation during FY 2021, five will end prior to September 30, 2021. Therefore, consistent with previous practice, we prorate the cost amounts for these hospitals by the fraction of total months in the demonstration period of participation that fall within FY 2021 out of the total of 12 months in the fiscal year. For example, for a hospital whose period of performance ends June 30, 2021, this prorating factor is 0.75. We sum these hospital-specific amounts to arrive at a total general amount representing the costs for covered inpatient hospital services, including swing beds, across the total 23 hospitals participating during FY 2021.

Then, we multiply this amount by the FYs 2019, 2020 and 2021 IPPS market basket percentage increases, which are formulated by the CMS Office of the Actuary. (We are using the proposed market basket percentage increase for FY 2021, which can be found at section II.A. of the Addendum to this proposed rule). The result for the 23 participating hospitals is the general estimated reasonable cost amount for covered inpatient hospital services for FY 2021.

Consistent with our methods in previous years for formulating this estimate, we are applying the IPPS market basket percentage increases for FYs 2019 through 2021 to the applicable estimated reasonable cost amount (previously described) in order to model the estimated FY 2021 reasonable cost amount under the demonstration. We believe that the IPPS market basket percentage increases appropriately indicate the trend of increase in inpatient hospital operating costs under the reasonable cost methodology for the years involved.

Step 2: For each of the participating hospitals, we identify the estimated amount that would otherwise be paid in FY 2021 under applicable Medicare payment methodologies for covered inpatient hospital services, including swing beds (as indicated on the same set of ''as submitted'' cost reports as in Step 1), if the demonstration were not implemented. (Also, similar to step 1, we are prorating the amounts for hospitals whose period of participation ends prior to the end of FY 2021 by the fraction of total months in the demonstration period of participation for the hospital that fall within FY 2021 out of the total of 12 months in the fiscal year). We sum these hospital-specific amounts, and, in turn, multiply this sum by the FYs 2019, 2020 and 2021 IPPS applicable percentage increases. (Again, for FY 2021, we are using the proposed applicable percentage increase, per section II.A. of the Addendum of this proposed rule). This methodology differs from Step 1, in which we apply the market basket percentage increases to the hospitals' applicable estimated reasonable cost amount for covered inpatient hospital services. We believe that the IPPS applicable percentage increases are appropriate factors to update the estimated amounts that generally would otherwise be paid without the demonstration. This is because IPPS payments constitute the majority of payments that would otherwise be made without the demonstration and the applicable percentage increase is the factor used under the IPPS to update the inpatient hospital payment rates.

Step 3: We subtract the amount derived in Step 2 from the amount derived in Step 1. According to our methodology, the resulting amount indicates the total difference for the 23 hospitals (for covered inpatient hospital services, including swing beds), which will be the general estimated amount of the costs of the demonstration for FY 2021.

For this proposed rule, the resulting amount is $40,804,704, which we are incorporating into the budget neutrality offset adjustment for FY 2021. This estimated amount is based on the specific assumptions regarding the data sources used, that is, recently available ''as submitted'' cost reports and historical update factors for cost and payment. If updated data become available prior to the final rule, we would use them as appropriate to estimate the costs for the demonstration program for FY 2021 in accordance with our methodology for determining the budget neutrality estimate).

(3) Reconciling Actual and Estimated Costs of the Demonstration for Previous Years

As described earlier, we have calculated the difference for FYs 2005 through 2015 between the actual costs of the demonstration, as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

At this point, not all cost reports have been finalized for the 19 hospitals that completed cost report periods under the demonstration payment methodology beginning in FY 2016. If the entire set of finalized cost reports is available prior to the FY 2021 IPPS/LTCH final rule, we will include in the final budget neutrality offset amount for FY 2021 the difference between the actual cost as determined from these cost reports and the estimated amount identified in the final rule for FY 2016 in the final rule for the upcoming fiscal year.

(4) Total Proposed Budget Neutrality Offset Amount for FY 2020

Therefore, for this FY 2021 IPPS/LTCH PPS proposed rule, the budget neutrality offset amount for FY 2021 is based on the amount determined under section II.A. of the Addendum of this proposed rule, representing the difference applicable to FY 2021 between the sum of the estimated reasonable cost amounts that would be paid under the demonstration to the 23 hospitals participating in the fiscal year for covered inpatient hospital services and the sum of the estimated amounts that would generally be paid if the demonstration had not been implemented. This estimated amount is $40,804,704.

P. Market-Based MS–DRG Relative Weight Proposed Data Collection and Potential Change in Methodology for Calculating MS–DRG Relative Weights

1. Overview

On October 12, 2017, President Trump issued Executive Order (E.O.) 13813 on *Promoting Healthcare Choice and Competition Across the United States.* E.O. 13813 directs the administration, to the extent consistent with law, to facilitate, ''the development and operation of a healthcare system that provides high-quality care at affordable prices for the American people,'' by increasing consumer choice and promoting competition in healthcare markets and by removing and revising government regulation.

As a result of E.O. 13813, the Secretary published a report entitled, ''Reforming America's Healthcare System Through Choice and Competition,'' which recognized the importance of price transparency in bringing down the cost of healthcare. Building on the importance of transparency in healthcare pricing, in accordance with the President's E.O. on *Improving Price and Quality Transparency in American Healthcare to Put Patients First* (issued on June 24, 2019), we proposed in the CY 2020 Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems (OPPS/ASC PPS) proposed rule to establish requirements for all hospitals in the United States to make available to the public their standard charges for the items and services they provide, including their payer-specific negotiated charges for all of their items and services, and a more consumer-friendly display of their payer-specific negotiated charges for certain selected shoppable services (84 FR 39571). In the CY 2020 OPPS/ASC PPS, Price Transparency Requirements for Hospitals to Make Standard Charges Public final rule (CMS–1717–F2, referred to herein as the Hospital Price Transparency final rule) (84 FR 65538), we finalized these requirements for all hospitals in the United States for making hospital standard charges available to the public, beginning January 1, 2021, as well as an enforcement scheme to enforce those requirements. We also finalized that the term ''standard charge'' means the regular rate established by the hospital for an item or service provided to a specific group of paying patient, and includes all of the following as defined in our regulations at 45 CFR 180.20: (1) Gross charge; (2) payer-specific negotiated charge; (3) de-identified minimum negotiated charge; (4) de-identified maximum negotiated charge; and (5) discounted cash price.

There are three broad types of hospital rates, depending on the patient and payer: (1) Medicaid and Medicare fee for service (FFS) rates; (2) negotiated rates with private insurers or health plans; and (3) uninsured or self-pay, as discussed in the Hospital Price Transparency final rule (84 FR 65538).

Medicaid FFS rates are dictated by each State and tend to be at the lower end of market rates. Medicare FFS rates are determined by CMS and those rates tend to be higher than Medicaid rates within a state. Privately negotiated rates vary with the competitive structure of the geographic market and usually tend to be somewhat higher than Medicare rates, but in some areas of the country the two sets of rates tend to converge. Uninsured or self-pay patient rates are often the same as chargemaster[466] (gross) rates, which are usually highly inflated in order to secure higher payments from Medicare and private payers.[467]

Under the old hospital reimbursement system, the more services a hospital provided and longer a patient's stay, the greater the reimbursement. Congress, recognizing that the reimbursement system created disincentives to provide efficient care, enacted in 1983 a prospective payment system. The primary objective of the prospective payment system is to create incentives for hospitals to operate efficiently and minimize unnecessary costs while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries.

To partly compensate hospitals for certain overly costly hospitalizations, hospitals may receive an ''outlier'' payment which is based on the hospital's billed charges, adjusted to cost, in comparison to the payment that would otherwise be received and an outlier threshold (see 42 CFR 412.84). To determine whether an individual case would qualify for an outlier payment, the hospital's cost-to-charge ratio (CCR) is applied to the covered charges to estimate the costs of the case. In the late 1990s, many hospitals began manipulating or gaming that ratio to make it easier to qualify for outlier payments. The larger the charges, the smaller the ratio, but it takes time for the ratio to be updated (unless the hospital directly updated their cost-to-charge ratio with the MAC). Thus, by way of example, if a hospital had a cost-to-charge ratio 1 to 5, or 20 percent, then a pill which cost the hospital $1 to purchase might be billed to a patient at $5. However, if the hospital doubled the charge to the patient to $10, the corresponding change in its ratio would take time to be updated. Its costs might look like $2 instead of $1 in the interim. Rule changes such as those made in the IPPS/LTCH PPS Change in Methodology for Determining Payment for Extraordinarily High-Cost Cases (Cost Outliers) Final Rule (June 9, 2003; 68 FR 34497 through 34504), we established policies related to updating CCRs and the reconciliation of outlier payments, which reduced such manipulation (for more information regarding these changes we refer readers to: *https://www.govinfo.gov/content/pkg/FR-2003-06-09/pdf/03-14492.pdf*). Nevertheless, some hospitals' charges do not reflect market rates. Hospital bills that are generated off these chargemaster rates can be inherently unreasonable when judged against prevailing market rates.

Recognizing that chargemaster (gross) rates rarely reflect the true market costs, we believe that by reducing our reliance on the hospital chargemaster, we can adjust Medicare payment rates so that they reflect the relative market value for inpatient items and services. Additionally, we have received public feedback that the Medicare program's use of hospital gross charges for some payments in ratesetting has served as the most significant barrier to hospitals' efforts to rebase their chargemasters.

[466] CMS currently refers to chargemasters as a Charge Description Master or CDM, which means the list of all individual items and services maintained by a hospital for which the hospital has established a charge.

[467] Richman BD, et al. Battling the Chargemaster: A Simple Remedy to Balance Billing for Unavoidable Out-of-Network Care. Am J Manag Care. 2017;23(4):e100–e105 Available at: *https://www.ajmc.com/journals/issue/2017/2017-vol23-n4/battling-the-chargemaster-a-simple-remedy-to-balance-billing-for-unavoidable-out-of-network-care.*

These stakeholders argued that this Medicare payment process serves as a barrier for rebasing changes, because any reduction in charges requires coordination with Medicare, Medicaid and commercial health plans so that any changes occur in a revenue-neutral manner to the hospital. We continue to believe that our existing administrative mechanisms for hospitals to voluntarily lower their charges adequately address these commenters' concerns. Specifically, if a hospital is planning on voluntarily lowering its charges, it can request a CCR change pursuant to 42 CFR 412.84(i)(1) and as also discussed in prior rulemaking (84 FR 42630). Nevertheless, we agree in general that a decreased reliance on hospital chargemasters in Medicare payment would be desirable, if an appropriate alternative mechanism exists and is permitted by statute.

Furthermore, the goal of reducing the Medicare program's reliance on the chargemaster and adopting payment strategies that are more reflective of the commercial insurance market was showcased within E.O. 13890 on *Protecting and Improving Medicare for Our Nation's Seniors,* which President Trump issued on October 3, 2019. The E.O. described the market benefits provided under the Medicare Advantage program as providing, ''efficient and value-based care through choice and private competition, and has improved aspects of the Medicare program that previously failed seniors.'' E.O. 13890 then directed the Medicare program to adopt and implement those market-based recommendations developed pursuant to Executive Order 13813 of October 12, 2017 (Promoting Healthcare Choice and Competition Across the United States), and published in the Administration's report on, ''Reforming America's Healthcare System Through Choice and Competition.'' Furthermore, E.O. 13890 directed HHS to identify, ''approaches to modify Medicare FFS payments to more closely reflect the prices paid for services in MA and the commercial insurance market, to encourage more robust price competition, and otherwise to inject market pricing into Medicare FFS reimbursement.'' E.O. 13890 directed the Secretary, in consultation with other partners, to produce a report with approaches to achieve the goal of establishing more market-based pricing within Medicare FFS reimbursements within 180 days of the E.O.'s issuance. (For additional information on E.O. 13890, we refer readers to: *https://www.federalregister.gov/documents/2019/10/08/2019-22073/protecting-and-improving-medicare-for-our-nations-seniors.*) (For more information on E.O. 13813, we direct readers to: *https://www.federalregister.gov/documents/2017/10/17/2017-22677/promoting-healthcare-choice-and-competition-across-the-united-states.*)

In order to reduce the Medicare program's reliance on the hospital chargemaster, thereby advancing the critical goals of E.O.s 13813 and 13890, and to support the development of a market-based approach to payment under the Medicare FFS system, we are proposing that hospitals would be required to report certain market-based payment rate information on their Medicare cost report for cost reporting periods ending on or after January 1, 2021, to be used in a potential change to the methodology for calculating the IPPS MS–DRG relative weights to reflect relative market-based pricing.

As described further in section IV.P.2.c. of the preamble of this proposed rule, we are specifically proposing that hospitals would report on the Medicare cost report two median payer-specific negotiated charges ''by MS–DRG.'' For a third-party payer that uses the same MS–DRG patient classification system used by Medicare, the payer-specific negotiated charges that the hospital uses to calculate the median by MS–DRG would be the payer-specific negotiated charges the hospital negotiated with that third party payer for the MS–DRG to which the patient discharge was classified. However, we recognize that not all third party payers use the MS–DRG patient classification system. For those third party payers that do not, the payer-specific negotiated charges they negotiate with hospitals would be based on the system used by that third party payer, such as per diem rates or APR–DRGs. In that case, the hospital would determine and report the median payer-specific negotiated charges by MS–DRG using its payer-specific negotiated charges for the same or similar package of services that can be crosswalked to an MS–DRG. For simplicity, we refer to this data collection herein as collecting the median payer-specific negotiated charge by MS–DRG. We believe the use of these data in the MS–DRG relative weight setting methodology would represent a significant and important step in reducing the Medicare program's reliance on hospital chargemasters, and would better reflect relative market-based pricing in Medicare FFS inpatient reimbursements.

Specifically, we are proposing that hospitals would report on the Medicare cost report: (1) The median payer-specific negotiated charge that the hospital has negotiated with all of its Medicare Advantage (MA) organizations (also referred to as MA organizations) payers, by MS–DRG; and (2) the median payer-specific negotiated charge the hospital has negotiated with all of its third-party payers, which would include MA organizations, by MS–DRG. The market-based rate information we are proposing to collect on the Medicare cost report would be the median of the payer-specific negotiated charges by MS–DRG, as described previously, for a hospital's MA organization payers and all of its third party payers. The payer-specific negotiated charges used by hospitals to calculate these medians would be the payer-specific negotiated charges for service packages that hospitals are required to make public under the requirements we finalized in the Hospital Price Transparency final rule (84 FR 65524) that can be cross-walked to an MS–DRG. If we finalize this market-based data collection proposal, hospitals would use the payer-specific negotiated charge data that they would be required to make public, as a result of the Hospital Price Transparency final rule, to then calculate the median payer-specific negotiated charges (as described further in section IV.P.2.c. of this proposed rule) to report on the Medicare cost report. We believe that because hospitals are already required to publically report payer-specific negotiated charges, in accordance with the Hospital Price Transparency final rule, that the additional calculation and reporting of the median payer-specific negotiated charge will be less burdensome for hospitals.

We are also seeking comment on a potential change to the methodology for calculating the IPPS MS–DRG relative weights to incorporate this market-based rate information, beginning in FY 2024, which we may consider adopting in the FY 2021 IPPS/LTCH PPS final rule. As described in greater detail in section IV.P.d. of the preamble of this proposed rule, this alternative methodology would involve using hospitals' reported median payer-specific negotiated charges to develop market-based IPPS payments to reflect the relative hospital resources used to provide inpatient services to patients. The use of payer-specific negotiated charges would replace the current use of gross charges that are reflected on a hospital's chargemaster and cost information from Medicare cost reports for the development of the IPPS MS–DRG relative weights. CMS is requesting comment on the use of hospitals' reported median payer-specific

negotiated charge data, which would be calculated using a subset of the payer-specific negotiated charges that, starting January 1, 2021, hospitals are required to make public under 45 CFR part 180. As proposed, the median payer-specific negotiated charges calculated and submitted by hospitals for each MS–DRG would be limited to charges hospitals have negotiated with: (1) MA organizations; and (2) third party payers, including MA organizations. As noted previously, we believe the use of payer-specific negotiated charge data in the MS–DRG relative weight setting methodology would help reduce the Medicare program's reliance on hospital chargemasters, and would reflect relative market-based pricing in Medicare FFS inpatient reimbursements.

2. Market-Based MS–DRG Relative Weight Estimation

a. Overview

Section 1886(d)(4)(A) of the Act states that the Secretary shall establish a classification of inpatient hospital discharges by diagnosis-related groups and a methodology for classifying specific hospital discharges within these groups. Section 1886(d)(4)(B) of the Act states that for each such diagnosis-related group the Secretary shall assign an appropriate weighting factor which reflects the relative hospital resources used with respect to discharges classified within that group compared to discharges classified within other groups. For the reasons discussed, we believe the use of market-based data, to be collected on the Medicare cost report, may support the development of an appropriate market-based approach to payment under the Medicare FFS system by incorporating such data into the estimation of the relative hospital resources used with respect to discharges classified within a single MS–DRG compared to discharges classified within other MS–DRGs, as required by statute.

We currently use a cost-based methodology to estimate an appropriate weight for each MS–DRG. These weights reflect the relative hospital resources used with respect to discharges classified within that MS–DRG compared to discharges classified within other MS–DRGs. The current cost-based methodology primarily uses hospital charges from the MedPAR claims data and cost report data from the Healthcare Cost Report Information System (HCRIS) to establish the MS–DRG relative weights (the collection of cost report data is authorized under OMB 0938–0050, which is used to produce both files). (We refer readers to section II.E. of this proposed rule for the discussion of the methodology we are proposing to use to recalibrate the FY 2021 MS–DRG cost-based relative weights.) This cost-based methodology was originally proposed and finalized with revisions in the FY 2007 IPPS rulemaking (71 FR 24006 through 24011 and 71 FR 47881 through 47898); it has since been modified in subsequent IPPS rulemaking. Prior to the FY 2007 IPPS rulemaking, we used a charge-based DRG relative weight methodology.

Hospitals are already required to make their payer-specific negotiated charge data for service packages publicly available under the Hospital Price Transparency final rule. Consistent with the desire to reduce the Medicare program's reliance on the hospital chargemaster, as well as to inject market pricing into Medicare FFS reimbursement, we believe it is again appropriate to reconsider our current approach to calculating the MS–DRG relative weights. For these reasons, we have reexamined the need to continue to use the charges on IPPS hospital claims, in conjunction with charge and cost data on hospital cost reports, to estimate the MS–DRG relative weights. In particular, we are considering whether the payer-specific negotiated charges by MS–DRG for MA organizations, or alternatively the payer-specific negotiated charges by MS–DRG for all third party payers (we note that this would include MA organization data), or some other approach that would reflect relative market-based charges by MS–DRG, could provide an appropriate basis for estimating the relative hospital resources used with respect to discharges classified within a single MS–DRG compared to discharges classified within other MS–DRGs, as required by statute.

b. Research Comparing Medicare, Medicare Advantage Organization, and Commercial Payment Rates

As an initial matter, we focused on the charges negotiated between hospitals and MA organizations given that MA plans are often paying for the same units and types of services as fee-for-service (FFS) Medicare. As part of our consideration of this issue, we looked to existing public research on the relationship between Medicare FFS inpatient payment rates and the payment rates negotiated between hospitals and MA organizations. Berenson et al.[468] surveyed senior hospital and health plan executives and found that MA plans nominally pay only 100 to 105 percent of traditional Medicare rates and, in real economic terms, possibly less. Respondents broadly identified three primary reasons for near payment equivalence: Statutory and regulatory provisions that limit out-of-network payments to traditional Medicare rates, de facto budget constraints that MA plans face because of the need to compete with traditional Medicare and other MA plans, and a market equilibrium that permits relatively lower MA rates as long as commercial rates remain well above the traditional Medicare rates.

We next researched empirically based comparisons of Medicare FFS rates, MA organization rates, and rates of other commercial payers. Baker et al.[469] used data from Medicare and the Health Care Cost Institute (HCCI) to identify the prices paid for hospital services by FFS Medicare, MA plans, and commercial insurers in 2009 and 2012. They calculated the average price per admission, and its trend over time, in each of the three types of insurance for fixed baskets of hospital admissions across metropolitan areas. After accounting for differences in hospital networks, geographic areas, and case-mix between MA and FFS Medicare, they found that MA plans paid 5.6 percent less for hospital services compared to FFS Medicare. For the time period studied, the authors suggest that at least one channel through which MA plans paid lower prices was by obtaining greater discounts on types of FFS Medicare admissions that were known to have very short lengths-of-stay. They also found that the rates paid by commercial plans were much higher than those of either MA or FFS Medicare, and growing. At least some of this difference they indicated came from the much higher prices that commercial plans paid for profitable service lines.

Maeda and Nelson[470] also analyzed data from the HCCI in their research. They compared the hospital prices paid by MA organizations and commercial plans with Medicare FFS prices using 2013 claims from the HCCI. The HCCI claims were used to calculate hospital prices for private insurers, and

[468] Berenson RA, Sunsine JH, Helms D, Lawton E. Why Medicare Advantage plans pay hospitals traditional Medicare prices. *Health Aff (Millwood).* 2015;34(8):1289–1295.

[469] Baker LC, Bundorf MK, Devlin AM, Kessler DP. Medicare Advantage plans pay less than traditional Medicare pays. *Health Aff (Millwood).* 2016;35(8):1444–1451.

[470] Maeda JLK, Nelson L. How Do the Hospital Prices Paid by Medicare Advantage Plans and Commercial Plans Compare with Medicare Fee-for-Service Prices? *The Journal of Health Care Organization, Provision, and Financing.* 2018;55(1–8).

Medicare's payment rules were used to estimate Medicare FFS prices. The authors focused on stays at acute care hospitals in metropolitan statistical areas (MSAs). They found MA prices to be roughly equal to Medicare FFS prices, on average, but commercial prices were 89 percent higher than FFS prices. In addition, commercial prices varied greatly across and within MSAs, but MA prices varied much less. The authors considered their results generally consistent with the Baker et al. study findings in that hospital payments by MA plans were much more similar to Medicare FFS levels than they were to commercial payment levels, although they noted that they used slightly different methods to calculate Medicare FFS prices.

In their study, Maeda and Nelson also examined whether the ratio of MA prices to FFS prices varied across DRGs to assess whether there were certain DRGs for which MA plans tended to pay more or less than FFS. They ranked the ratio of MA prices to FFS prices and adjusted for outlier payments. The authors state that they found that, ''there were some DRGs where the average MA price was much higher than FFS and there were some DRGs where the average MA price was a bit lower than FFS.'' For example, for the time period in question, on average, MA plans paid 129 percent more than FFS for rehabilitation stays (DRG 945), 33 percent more for depressive neuroses (DRG 881), and 27 percent more for stays related to psychoses (DRG 885). But MA plans paid an average of 9 percent less than FFS for stays related to pathological fractures (DRG 542) and wound debridement and skin graft (DRG 464) (see Online Appendix Table 5 from their study). The authors state these results suggest that there may be certain services where MA plans pay more than FFS possibly because the FFS rates for those services are too low, but that there may be other services where MA plans pay less than FFS possibly because the FFS rates for those DRGs are too high (Maeda, Nelson, 2018 p. 5).

Taken as a whole, we believe this body of research suggests that payer-specific charges negotiated between hospitals and MA organizations are generally well-correlated with Medicare IPPS payment rates, and payer-specific charges negotiated between hospitals and other commercial payers are generally not as well-correlated with Medicare IPPS payment rates. With respect to either type of payer-specific negotiated charges, there may be instances where those negotiated charges may reflect the relative hospital resources used within an MS–DRG differently than our current cost-based methodology.

Considering the public availability of payer-specific negotiated charges starting in CY 2021 and the desire to reduce the Medicare program's reliance on the hospital chargemaster to thereby address the directives in E.O.s 13813 and 13890, we believe we could adjust the methodology for calculating the MS–DRG relative weights to reflect a more market-based approach under our existing authority under sections 1886(d)(4)(A) and 1886(d)(4)(B) of the Act.

c. Proposed Market-Based Data Collection

For the reasons discussed, in order to support the development of a relative market-based payment methodology under the IPPS, as well as satisfy E.O.s 13813 and E.O. 13890 by reducing our reliance on the hospital chargemaster, we propose to collect market-based payment rate information on Medicare cost reports beginning with cost reporting periods ending on or after January 1, 2021. Sections 1815(a) and 1833(e) of the Act provide that no Medicare payments will be made to a provider unless it has furnished the information, as may be requested by the Secretary, to determine the amount of payments due the provider under the Medicare program. We require that providers follow reasonable cost principles under section 1861(v)(1)(A) of the Act when completing the Medicare cost report. Under the regulations at 42 CFR 413.20 and 413.24, we define adequate cost data and require cost reports from providers on an annual basis. As previously discussed, the collection of this market-based data on the Medicare cost report would allow for the adoption of market-based strategies in determining Medicare FFS payments and would reduce our reliance on the hospital chargemaster for ratesetting purposes, in particular for purposes of estimating the appropriate weighting factor to reflect the relative hospital resources used with respect to hospital discharges, as required under sections 1886(d)(4)(B) and 1886(d)(4)(C) of the Act.

First, we propose to collect on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MA organization payers, by MS–DRG. Second, we propose to collect on the Medicare cost report the median payer-specific negotiated charge the hospital has negotiated with all of its third-party payers, which would include MA organizations, by MS–DRG. We propose to collect the median of the hospital payer-specific negotiated charges, because the median is a common measure of central tendency that is less influenced by outlier values. As described in more detail later in this section, we are proposing to collect the hospital's median payer-specific negotiated charges by MS–DRG, which would be calculated using the payer-specific negotiated charge data for service packages that hospitals are required to make public under the Hospital Price Transparency final rule that can be cross-walked to an MS–DRG.

Medicare certified providers, such as Medicare certified hospitals, are required to submit an annual cost report to their Medicare Administrative Contractor (MAC). The Medicare cost report contains provider information such as facility characteristics, cost and charges by cost center, in total and for Medicare, Medicare settlement data, and financial statement data. The cost report must be submitted in a standard (ASCII) electronic cost report (ECR) format. CMS maintains the cost report data in the HCRIS dataset. The HCRIS data supports our reimbursement policymaking, congressional studies, legislative health care reimbursement initiatives, Medicare profit margin analysis, and relative weight updates. As such, every data point from hospital cost reports beginning on or after May 1, 2010 is reflected on the HCRIS dataset, and available for public access and use.

Accordingly, if we were to finalize this proposal to collect the proposed market-based information (specifically, the median payer-specific negotiated charges negotiated between a hospital and all its MA organization payers, by MS–DRG and the median payer-specific negotiated charges negotiated between a hospital and all its third party payers, by MS–DRG) on the cost report, this data would become publicly accessible on the HCRIS dataset in a de-identified manner and would be usable for analysis by third parties. The data would, by definition, be de-identified since we are proposing that the hospital calculate the median rate (that is, the specific rate that is negotiated between a hospital and a specific third party payer for an MS–DRG would not be reported and need to be de-identified). For more information or to obtain HCRIS data we refer readers to: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Cost-Reports-by-Fiscal-Year.html*.

A payer-specific negotiated charge is the charge that a hospital has negotiated with a third party payer for an item or service provided by the hospital. We

note that the definition of third party payer, for the purposes of this proposed rule and data collection proposal, includes MA organizations. As described later in this section, we are proposing that the two median payer-specific negotiated charges by MS–DRG that hospitals would be required to report on the Medicare cost report for cost reporting periods ending on or after January 1, 2021, would be calculated using the payer-specific negotiated charges for service packages that hospitals are required to make publically available under the Hospital Price Transparency final rule that can be cross-walked to a MS–DRG.

The Hospital Price Transparency final rule requires that hospitals make publicly available via the internet their standard charges (including, as applicable, gross charges, payer-specific negotiated charges, de-identified minimum negotiated charges, de-identified maximum negotiated charges, and discounted cash prices) in two different ways: (1) A single machine-readable file containing a list of standard charges for all items and services provided by the hospital that complies with requirements described in 45 CFR 180.50; and (2) a consumer-friendly list of standard charges 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, that complies with requirements described in 45 CFR 180.60. For purposes of this proposed rule and data collection proposal, we propose that hospitals would calculate the median payer-specific negotiated charge by MS–DRG using the payer-specific negotiated charge data by MS–DRG from the single machine-readable file for all items and services (as required by the Hospital Price Transparency final rule) and not the version of payer-specific negotiated charge data included within the file for public production, in a consumer-friendly manner, of CMS-specified and hospital-selected shoppable services.

The following is our proposed methodology for how each hospital would calculate its median payer-specific negotiated charge for MA organizations by MS–DRG and its median payer-specific negotiated charge for all third party payers by MS–DRG. As we are proposing to collect this data for purposes of incorporating market-based rate information into the IPPS payment methodologies, the median payer-specific negotiated charge data would be reported by MS–DRG for consistency with the grouping system that we currently use to classify inpatient hospital discharges under section 1886(d)(4)(A) of the Act. Therefore, as referenced previously, hospitals would report the payer-specific negotiated charges by MS–DRG and not by another DRG classification system.

To determine the median payer-specific negotiated charge for MA organizations for a given MS–DRG, a hospital would list, by MS–DRG, each discharge in its cost reporting period that was paid for by an MA organization, and the corresponding payer-specific negotiated charge that was negotiated as payment for items and services provided for that discharge. The median payer-specific negotiated charge for payers that are MA organizations, for that MS–DRG, would be the median payer-specific negotiated charge in that list of discharges.

A simplified example for the purpose of illustrating this process is as follows. Hospital A has negotiated four different payer-specific charges with four MA organizations for hypothetical MS–DRG 123. The four payer-specific negotiated charges are $7,300, $7,400, $7,600, and $7,700. In its cost reporting period, Hospital A had 3 discharges for which $7,300 was the basis for payment for the items and services provided for that discharge, 2 discharges for which $7,400 was the basis for payment for the items and services provided for that discharge, 1 discharge for which $7,600 was the basis for payment for the items and services provided for that discharge, and 1 discharge for which $7,700 was the basis for payment for the items and services provided for that discharge. Therefore, for Hospital A, the payer-specific negotiated charges for its list of discharges paid for by MA organizations in its cost reporting period for MS–DRG 123 is $7,300, $7,300, $7,300, $7,400, $7,400, $7,600, and $7,700. The median of this list is $7,400. Hospital A's median payer-specific negotiated charge for MS–DRG 123 for payers that are MA organizations would be $7,400.

Our proposed methodology for how each hospital would calculate its median payer-specific negotiated charge for a given MS–DRG for all third party payers, including MA organizations, is the same as the process outlined above.

For purposes of this calculation, we are proposing to define the term, ''payer-specific negotiated charge'' as the charge that a hospital has negotiated with a third party payer for an item or service. We propose to use this definition of the payer-specific negotiated charge, because it would capture the charges that are negotiated between hospitals and third party payers, including MA organizations, and can provide the data needed to evaluate the use of market-based information for payment purposes within the MS–DRG relative weight calculation. For consistency, the definition of payer-specific negotiated charge that we are proposing to use for purposes of this proposal is the same definition of ''payer-specific negotiated charge'' that we finalized for purposes of our requirements for hospitals to make their standard charges available to the public under the Hospital Price Transparency final rule. We are also proposing to define, ''items and services'' as all items and services, including individual items and services and service packages, that could be provided by a hospital to a patient in connection with an inpatient admission for which the hospital has established a standard charge. An MS–DRG, as established by CMS under the MS–DRG classification system, is a type of service package consisting of items and services based on patient diagnosis and other characteristics. We propose this definition of items and services, because we believe it captures the types of items and services, including service packages, that a hospital would use to calculate and report the median payer-specific negotiated charge for each MS–DRG to support the use of market-based rate information by MS–DRG within the MS–DRG relative weight calculation. This proposed definition is also the same definition of items and services that we finalized for purposes of our requirements for hospitals to make their standard charges available to the public under the Hospital Price Transparency final rule, except that we have omitted the reference to outpatient department visits, because we would not require hospitals to calculate the median of their payer-specific negotiated charges for items and services provided in the hospital outpatient setting under our proposal.

For purposes of this calculation, an MA organization is defined in 42 CFR 422.2; namely, an MA organization means a public or private entity organized and licensed by a State as a risk-bearing entity (with the exception of provider-sponsored organizations receiving waivers) that is certified by CMS as meeting the MA contract requirements.

For purposes of this calculation, we propose to define third party payer as an entity that is, by statute, contract, or agreement, legally responsible for payment of a claim for a healthcare item or service. As the reference to ''third party'' suggests, this definition excludes an individual who pays for a healthcare

item or service that he or she receives (such as self-pay patients). We propose to use this definition of third party payer, because these are the types of entities that contract with hospitals to reimburse for services on behalf of patients. This definition is also the definition of third party payer finalized in the Hospital Price Transparency final rule.

We welcome public comment on the proposed definitions of payer-specific negotiated charge, items and services, and third party payer. As discussed previously, we recognize that hospitals may negotiate rates in several ways and under different circumstances. For example, hospitals may negotiate rates with third party payers as a percent discount off chargemaster rates, on a per diem basis, or by MS–DRG or other similar DRG system. We also recognize that there may be hospitals that do not negotiate charges for service packages by MS–DRG or for service packages that may be crosswalked to an MS–DRG. Therefore, we seek comment on whether hospitals' median payer-specific negotiated charges across all types of payment methodologies should be included in the determination of the median payer-specific negotiated charge for the conditions and procedures that are classified under the MS–DRG system and if so, how the proposed definitions should be modified to encompass these other types of negotiation strategies or methodologies. We also seek comment on the appropriateness of using MS–DRGs or MS–DRG equivalents for this methodology, as well as whether we should potentially collect this information for payers that use MS–DRGs separately from payers that use other DRG systems. Furthermore, we seek comment on alternatives that would capture market-based information for the potential use in Medicare FFS payments. We also welcome comments and suggested refinements to our proposed definitions, as well as market-based alternatives that we should consider when identifying the market-based information that reflects the charges that a hospital negotiates for a specific MS–DRG.

In order to address some of the issues noted previously, as an alternative, we considered requiring hospitals to submit a median negotiated reimbursement amount across all MA organizations and across all third party payers (including MA organizations) by MS–DRG (or by an MS–DRG equivalent, such as APR–DRG). Under this alternative approach, we would define the ''negotiated reimbursement amount'' as the amount the hospital received as payment for the services rendered for a patient discharge, as classified under the MS–DRG system, and for which the hospital negotiated payment with a third party payer, including a MA organization, for hospital cost reporting periods ending on or after January 1, 2021. Hospitals would be required to determine and submit the median negotiated reimbursement amount for—(1) MA organizations; and (2) all third party payers, which includes MA organizations.

For example, a hospital may negotiate a case rate (that is, a payer-specific negotiated charge) of $30,000 with Payer A for a major joint replacement paid under the APR–DRG system (equivalent to MS–DRG 470). The hospital and payer have agreed to a stop loss threshold of $150,000 and that the hospital will be reimbursed at 50 percent off the gross (chargemaster) rate for each dollar charged over the stop-loss amount. Additionally, the hospital will be reimbursed for 60 percent of the cost of the implanted hardware, an amount that, in some cases, may be variable depending on the type or style of hardware implanted. In this example, the hospital's payer-specific negotiated charge for a major joint replacement (MS–DRG 470 equivalent) is $30,000. However, the resulting payment per discharge will vary, depending upon factors such as whether the patient's course of treatment exceeded the agreed-upon stoploss amount and the cost of the hardware implant.

We considered this alternative, because the median of the ''negotiated reimbursement amount'' is an amount that may take into consideration the actual and final payment amounts received by hospitals from third party payers, and MA organizations, for care of individuals, as compared to a standard charge negotiated for a particular service package identified by MS–DRG. We request comment on this alternative approach, which we believe may also provide a reasonable market-based estimate of the relative resources used to provide services for an MS–DRG, and may take into account the several ways that hospitals and third party payers negotiate charges.

We also seek comment on the relative burden of calculating and submitting a median negotiated reimbursement amount for MA organizations and for all other third party payers as compared to calculating and submitting the median payer-specific negotiated charge for MA organizations and median payer-specific negotiated charge for third party payers by MS–DRG payment system.

We are proposing that subsection (d) hospitals in the 50 states and DC, as defined at section 1886(d)(1)(B) of the Act, and subsection (d) Puerto Rico hospitals, as defined under section 1886(d)(9)(A) of the Act, would be required to report the median payer-specific negotiated charge information. Hospitals that do not negotiate payment rates and only receive non-negotiated payments for service would be exempted from this proposed data collection. We recognize that Critical Access Hospitals (CAHs) may, in some instances, negotiate payment rates; however, because CAHs are not subsection (d) hospitals and are not paid on the basis of MS–DRGs, CAHs would be excluded from this proposed data collection requirement. We are proposing that hospitals in Maryland, which are currently paid under the Maryland Total Cost of Care Model, would be exempt from this data collection requirement during the performance period of the Model. Examples of subsection (d) hospitals that only receive non-negotiated payment rates include hospitals operated by an Indian Health Program as defined in section 4(12) of the Indian Health Care Improvement Act or federally owned and operated facilities. We note that this proposed data collection requirement would apply to a smaller subset of hospitals as compared to the public reporting requirements under the Hospital Price Transparency final rule.

We are proposing that for cost reporting periods ending on or after January 1, 2021, a hospital would report on its cost report the median payer-specific negotiated charge for each MS–DRG for payers that are MA organizations, and the median payer-specific negotiated charge for each MS–DRG for all third party payers, which includes MA organizations. The required cost report reporting changes to accomplish this will be proposed in more detail in the Information Collection Request approved under OMB No. 0938–0050.

We are also proposing to amend 42 CFR 413.20(d)(3) to reflect this proposed requirement. Specifically, we are amending 42 CFR 413.20(d)(3) to require hospitals to report the median payer-specific negotiated charge by MS–DRG for payers that are MA organizations and for all third party payers on the Medicare cost report. We are proposing to capture this proposed data collection requirement in regulation at the new paragraph (d)(3)(i)(B). This proposed requirement would be effective for cost reporting periods ending on or after January 1, 2021.

As described previously, we are proposing to require hospitals to report

on the Medicare cost report both the hospital's median payer specific negotiated charge by MS–DRG for all MA organizations and the hospital's median payer-specific negotiated charge by MS–DRG for all third party payers, which includes MA organizations, for cost reporting periods ending on or after January 1, 2021. We note that we may also consider finalizing the collection of alternative market-based data, such as the median negotiated reimbursement amount as explained previously, or any refinements to the definition of median payer-specific negotiated charge, based on review of public comments. We are also considering a modification to the market based data collection proposal, to require only the reporting of the median payer-specific negotiated charge for MA organizations on the Medicare cost report. We are inviting public comments on our proposed data collection, as well as on these or other alternative data collections of payer-specific negotiated charges or other market-based information on the Medicare cost report, which we may consider finalizing in the FY 2021 IPPS/LTCH PPS final rule for cost reporting periods ending on or after January 1, 2021, after consideration of the comments received.

d. Potential Market Based MS–DRG Relative Weight Methodology Beginning in FY 2024

We are requesting comments on a potential new market-based methodology for estimating the MS–DRG relative weights, beginning in FY 2024, and which we may consider adopting in the FY 2021 IPPS/LTCH PPS final rule. This potential new market-based methodology would be based on the proposed median payer-specific negotiated charge information collected on the Medicare cost report. Implementing this potential new market-based methodology beginning in FY 2024 would allow sufficient time, should we finalize our data collection proposal, to collect and evaluate the median payer-specific negotiated charge data submitted on hospital cost reports and provide the public with information regarding our analysis in future rulemaking. Specifically, we are considering a methodology for estimating the MS–DRG relative weights using the median payer-specific negotiated charge for each MS–DRG for payers that are MA organizations, as described in this section. The MA program provides efficient and value-based care to patients through choice and private competition. We believe using the median payer-specific negotiated charge for payers that are MA organizations within the MS–DRG relative weight calculation would allow for a more market-based approach to determining Medicare FFS reimbursement and reduce our reliance on the hospital chargemaster.

We are also considering alternatives to this approach, such as the use of the median payer-specific negotiated charge for all third-party payers (instead of the median payer-specific negotiated charge for all MA organizations), or other alternative collections of payer-specific negotiated charges or other market-based information such as a median negotiated reimbursement amount that a hospital negotiates with its MA organizations or third party payers (as described further in section IV.P.2.c of the preamble of this proposed rule), within the MS–DRG relative weight methodology.

The same relative weight calculation described in this section would be used if an alternative to the median payer-specific negotiated charge was finalized to be collected on the Medicare cost report, as described in section IV.P.2.c. of the preamble of this proposed rule. We are inviting public comment on this potential change to the relative weight methodology beginning in FY 2024 to use the median payer-specific negotiated charge for MA organizations, as well as the other potential alternative data collections as described in section IV.P.2.c of the preamble of this proposed rule, which we may consider finalizing in the FY 2021 IPPS/LTCH PPS final rule. If we were to finalize a change in the IPPS FY 2021 rulemaking to incorporate payer-specific negotiated charges within the MS–DRG relative weight methodology, effective for FY 2024, we are open to adjusting any finalized policy, through future rulemaking, prior to the FY 2024 effective date. Should we finalize our data collection proposal, we would conduct further analysis based on the data received and provide an opportunity for public comment on that analysis, prior to the FY 2024 effective date.

• Step One: Standardize the Median MA Organizations Payer-Specific Negotiated Charges

In order to make the median MA organization payer-specific negotiated charges from the cost reports more comparable among hospitals, we would standardize the median payer-specific negotiated charges by removing the effects of differences in area wage levels, and cost-of living adjustments for hospital claims from Alaska and Hawaii, in the same manner as under the current MS–DRG relative weight calculation for those effects. We seek comment on the appropriate standardization for the median MA organization payer-specific negotiated charges, and any differences that should be taken into account in standardizing the median payer-specific negotiated charges for all third party payers.

• Step Two: Create a Single Weighted Average Standardized Median MA Organization Payer-Specific Negotiated Charge by MS–DRG Across Hospitals

For each MS–DRG, we would create a single weighted average across hospitals of the standardized median payer-specific negotiated charges. We would weight the standardized payer-specific negotiated charge for each MS–DRG for each hospital using that hospital's Medicare transfer-adjusted case count for that MS–DRG, with transfer adjusted case counts calculated exactly the same way as under the current MS–DRG relative weight methodology (84 FR 42621). We believe that using the Medicare transfer-adjusted case counts would be a reasonable approach to combining the data across hospitals because it would reflect relative volume and transfer activity (that is, larger hospitals responsible for more discharges would be weighted more heavily in the calculation, hospitals that transfer more often would be weighted less heavily), however, we may also consider alternative approaches, such as using the unadjusted Medicare case counts, or other alternative approaches based on the review of public comments. We seek comment on the most appropriate weighting factor for purposes of calculating a single weighted average standardized median MA organization payer-specific negotiated charge across hospitals.

• Step Three: Create a Single National Weighted Average Standardized Payer-Specific Negotiated Charge Across All MS–DRGs

We would create a single national weighted average across MS–DRGs of the results of Step Two, where the weights are the national Medicare transfer adjusted case counts by MS–DRG. If we were to use an alternative weighting factor to the Medicare transfer adjusted case counts in Step Two, as described previously, we would use that same alternative weighting factor here in Step Three.

• Step Four: Calculate the Market-Based Relative Weights

For each MS–DRG, the market-based relative weight would be calculated as the ratio of the single weighted average standardized median MA organization

payer-specific negotiated charge for that MS–DRG across hospitals from Step Two to the single national weighted average standardized median MA organization payer-specific negotiated charge across all MS–DRGs from Step Three.

• Step Five: Normalize the Market-Based Relative Weights

As under the current cost-based MS–DRG relative weight methodology, the market-based relative weights would be normalized by an adjustment factor so that the average case weight after recalibration would be equal to the average case weight before recalibration. As under the current cost-based relative weight estimation methodology, the normalization adjustment is intended to help ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

We are requesting comments on this potential new market-based methodology for estimating the MS–DRG relative weights beginning in FY 2024, including comments on any suggested refinements to this potential methodology or alternative approaches, which we may consider adopting in the FY 2021 IPPS/LTCH final rule. We note that some stakeholders have requested that we take a measured approach to any changes to adopt more market-based methods within Medicare IPPS reimbursements. We are therefore also interested in comments on whether, if we were to adopt some form of a market-based approach to the MS–DRG relative weight calculation, we should, for some period of time, continue to estimate and publicly provide the MS–DRG relative weights as calculated using our current cost-based estimation methodology. We are also interested in comments on whether we should provide a transition to any new market-based MS–DRG methodology, and, if so, on the appropriate design of any such transition. When we adopted the cost-based MS–DRG methodology for FY 2007 IPPS payments, we provided a 3-year transition from the charge-based MS–DRG relative weight calculation to the cost-based MS–DRG relative weight calculation (71 FR 47898). For the first year of the 3-year transition of the relative weights, the relative weights were based on a blend of 33 percent of the cost-based weights and 67 percent of the charge weights. In the second year of the transition, the relative weights were based on a blend of 33 percent of the charge weights and 67 percent of the cost-based weights. In the third year of the transition, the relative weights were based on 100 percent of the cost-based weights. We are requesting comments on whether CMS should provide a similar type of transition from a cost-based weight methodology to a market-based weight methodology, should we finalize the use of market-based data within the MS–DRG relative weight methodology.

Lastly, in future rulemaking, we may consider ways to further reduce the role of hospital chargemasters in Medicare IPPS payments and further reflect market-based approaches in Medicare FFS payments. In particular, we are requesting comments on alternatives to the current use of hospital charges in determining other inpatient hospital payments, including outlier payments and new technology add-on payments, to the extent permitted by law.

V. Proposed Changes to the IPPS for Capital-Related Costs

A. Overview

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services in accordance with a prospective payment system established by the Secretary. Under the statute, the Secretary has broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs. We initially implemented the IPPS for capital-related costs in the FY 1992 IPPS final rule (56 FR 43358). In that final rule, we established a 10-year transition period to change the payment methodology for Medicare hospital inpatient capital-related costs from a reasonable cost-based payment methodology to a prospective payment methodology (based fully on the Federal rate).

FY 2001 was the last year of the 10-year transition period that was established to phase in the IPPS for hospital inpatient capital-related costs. For cost reporting periods beginning in FY 2002, capital IPPS payments are based solely on the Federal rate for almost all acute care hospitals (other than hospitals receiving certain exception payments and certain new hospitals). (We refer readers to the FY 2002 IPPS final rule (66 FR 39910 through 39914) for additional information on the methodology used to determine capital IPPS payments to hospitals both during and after the transition period.)

The basic methodology for determining capital prospective payments using the Federal rate is set forth in the regulations at 42 CFR 412.312. For the purpose of calculating capital payments for each discharge, the standard Federal rate is adjusted as follows: (Standard Federal Rate) × (DRG Weight) × (Geographic Adjustment Factor (GAF)) × (COLA for hospitals located in Alaska and Hawaii) × (1 + Capital DSH Adjustment Factor + Capital IME Adjustment Factor, if applicable).

In addition, under § 412.312(c), hospitals also may receive outlier payments under the capital IPPS for extraordinarily high-cost cases that qualify under the thresholds established for each fiscal year.

B. Additional Provisions

1. Exception Payments

The regulations at 42 CFR 412.348 provide for certain exception payments under the capital IPPS. The regular exception payments provided under § 412.348(b) through (e) were available only during the 10-year transition period. For a certain period after the transition period, eligible hospitals may have received additional payments under the special exceptions provisions at § 412.348(g). However, FY 2012 was the final year hospitals could receive special exceptions payments. For additional details regarding these exceptions policies, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).

Under § 412.348(f), a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control. Additional information on the exception payment for extraordinary circumstances in § 412.348(f) can be found in the FY 2005 IPPS final rule (69 FR 49185 and 49186).

2. New Hospitals

Under the capital IPPS, the regulations at 42 CFR 412.300(b) define a new hospital as a hospital that has operated (under previous or current ownership) for less than 2 years and lists examples of hospitals that are not considered new hospitals. In accordance with § 412.304(c)(2), under the capital IPPS, a new hospital is paid 85 percent of its allowable Medicare inpatient hospital capital-related costs through its first 2 years of operation, unless the new hospital elects to receive full prospective payment based on 100 percent of the Federal rate. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725) for additional information on payments to new hospitals under the capital IPPS.

3. Payments for Hospitals Located in Puerto Rico

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57061), we revised the

regulations at 42 CFR 412.374 relating to the calculation of capital IPPS payments to hospitals located in Puerto Rico beginning in FY 2017 to parallel the change in the statutory calculation of operating IPPS payments to hospitals located in Puerto Rico, for discharges occurring on or after January 1, 2016, made by section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113). Section 601 of Public Law 114–113 increased the applicable Federal percentage of the operating IPPS payment for hospitals located in Puerto Rico from 75 percent to 100 percent and decreased the applicable Puerto Rico percentage of the operating IPPS payments for hospitals located in Puerto Rico from 25 percent to zero percent, applicable to discharges occurring on or after January 1, 2016. As such, under revised § 412.374, for discharges occurring on or after October 1, 2016, capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the capital Federal rate.

C. Proposed Annual Update for FY 2021

The proposed annual update to the national capital Federal rate, as provided for in 42 CFR 412.308(c), for FY 2021 is discussed in section III. of the Addendum to this FY 2021 IPPS/LTCH PPS proposed rule.

In section II.D. of the preamble of this FY 2021 IPPS/LTCH PPS proposed rule, we present a discussion of the MS–DRG documentation and coding adjustment, including previously finalized policies and historical adjustments, as well as the adjustment to the standardized amount under section 1886(d) of the Act that we are proposing for FY 2021, in accordance with the amendments made to section 7(b)(1)(B) of Public Law 110–90 by section 414 of the MACRA. Because these provisions require us to make an adjustment only to the operating IPPS standardized amount, we are not proposing to make a similar adjustment to the national capital Federal rate (or to the hospital-specific rates).

We also note that in section II.D.2.b. of the preamble of this proposed rule, we are proposing to create new MS–DRG 018 for cases that include procedures describing CAR T-cell therapies, and in section II.E.2.b. of this proposed rule, we are proposing to modify our relative weight methodology for proposed new MS–DRG 018 in order to develop a relative weight that is reflective of the typical costs of providing CAR T-cell therapies relative to other IPPS services. In addition, in section IV.I. of the preamble of this proposed rule, we discuss our proposal to apply an adjustment to the payment amount for clinical trial cases that would group to proposed new MS–DRG 018 for both operating IPPS payments and capital IPPS payments. We refer readers to section IV.I. of this preamble for additional details on the proposed payment adjustment for CAR T-cell therapy clinical trial cases.

VI. Proposed Changes for Hospitals Excluded From the IPPS

A. Proposed Rate-of-Increase in Payments to Excluded Hospitals for FY 2021

Certain hospitals excluded from a prospective payment system, including children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling. A per discharge limit (the target amount, as defined in § 413.40(a) of the regulations) is set for each hospital based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. For each cost reporting period, the updated target amount is multiplied by total Medicare discharges during that period and applied as an aggregate upper limit (the ceiling as defined in § 413.40(a)) of Medicare reimbursement for total inpatient operating costs for a hospital's cost reporting period. In accordance with § 403.752(a) of the regulations, religious nonmedical health care institutions (RNHCIs) also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously. Furthermore, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously.

As explained in the FY 2006 IPPS final rule (70 FR 47396 through 47398), beginning with FY 2006, we have used the percentage increase in the IPPS operating market basket to update the target amounts for children's hospitals, cancer hospitals, and RNHCIs. Consistent with the regulations at §§ 412.23(g) and 413.40(a)(2)(ii)(A) and (c)(3)(viii), we also have used the percentage increase in the IPPS operating market basket to update target amounts for short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. In the FYs 2014 and 2015 IPPS/LTCH PPS final rules (78 FR 50747 through 50748 and 79 FR 50156 through 50157, respectively), we adopted a policy of using the percentage increase in the FY 2010-based IPPS operating market basket to update the target amounts for FY 2014 and subsequent fiscal years for children's hospitals, cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. However, in the FY 2018 IPPS/LTCH PPS final rule, we rebased and revised the IPPS operating basket to a 2014 base year, effective for FY 2018 and subsequent years (82 FR 38158 through 38175), and finalized the use of the percentage increase in the 2014-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2018 and subsequent years. Accordingly, for FY 2021, the rate-of-increase percentage to be applied to the target amount for these hospitals would be the FY 2021 percentage increase in the 2014-based IPPS operating market basket.

For this FY 2021 IPPS/LTCH PPS proposed rule, based on IGI's 2019 fourth quarter forecast, we estimated that the 2014-based IPPS operating market basket update for FY 2021 would be 3.0 percent (that is, the estimate of the market basket rate-of-increase). Based on this estimate, the FY 2021 rate-of-increase percentage that would be applied to the FY 2020 target amounts in order to calculate the FY 2021 target amounts for children's hospitals, cancer hospitals, RNCHIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa would be 3.0 percent, in accordance with the applicable regulations at 42 CFR 413.40. However, we are proposing that if more recent data become available for the final rule, we would use such data, if appropriate, to calculate the final IPPS operating market basket update for FY 2021.

In addition, payment for inpatient operating costs for hospitals classified under section 1886(d)(1)(B)(vi) of the Act (which we refer to as ''extended neoplastic disease care hospitals'') for cost reporting periods beginning on or after January 1, 2015, is to be made as described in 42 CFR 412.526(c)(3), and payment for capital costs for these hospitals is to be made as described in 42 CFR 412.526(c)(4). (For additional

information on these payment regulations, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38321 through 38322).) Section 412.526(c)(3) provides that the hospital's Medicare allowable net inpatient operating costs for that period are paid on a reasonable cost basis, subject to that hospital's ceiling, as determined under § 412.526(c)(1), for that period. Under § 412.526(c)(1), for each cost reporting period, the ceiling was determined by multiplying the updated target amount, as defined in § 412.526(c)(2), for that period by the number of Medicare discharges paid during that period. Section 412.526(c)(2)(i) describes the method for determining the target amount for cost reporting periods beginning during FY 2015. Section 412.526(c)(2)(ii) specifies that, for cost reporting periods beginning during fiscal years after FY 2015, the target amount will equal the hospital's target amount for the previous cost reporting period updated by the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for the subject cost reporting period (79 FR 50197).

For FY 2021, in accordance with §§ 412.22(i) and 412.526(c)(2)(ii) of the regulations, for cost reporting periods beginning during FY 2021, the proposed update to the target amount for extended neoplastic disease care hospitals (that is, hospitals described under § 412.22(i)) is the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for FY 2021, which would be equal to the percentage increase in the hospital market basket index, which is estimated to be the percentage increase in the 2014-based IPPS operating market basket (that is, the estimate of the market basket rate-of-increase). Accordingly, the proposed update to an extended neoplastic disease care hospital's target amount for FY 2021 is 3.0 percent, which is based on IGI's 2019 fourth quarter forecast. Furthermore, we are proposing that if more recent data become available for the final rule, we would use such data, if appropriate, to calculate the IPPS operating market basket update for FY 2021.

B. Critical Access Hospitals (CAHs)

1. Background

Section 1820 of the Act provides for the establishment of Medicare Rural Hospital Flexibility Programs (MRHFPs), under which individual States may designate certain facilities as critical access hospitals (CAHs). Facilities that are so designated and meet the CAH conditions of participation under 42 CFR part 485, subpart F, will be certified as CAHs by CMS. Regulations governing payments to CAHs for services to Medicare beneficiaries are located in 42 CFR part 413.

2. Frontier Community Health Integration Project (FCHIP) Demonstration

a. Background and Overview

As discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42044 through 42701), section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275), as amended by section 3126 of the Affordable Care Act, authorized a demonstration project to allow eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries. The demonstration was titled ''Demonstration Project on Community Health Integration Models in Certain Rural Counties,'' and commonly known as the Frontier Community Health Integration Project (FCHIP) demonstration.

The authorizing statute stated the eligibility criteria for entities to be able to participate in the demonstration. An eligible entity, as defined in section 123(d)(1)(B) of Public Law 110–275, as amended, is an MRHFP grantee under section 1820(g) of the Act (that is, a CAH); and is located in a State in which at least 65 percent of the counties in the State are counties that have 6 or less residents per square mile.

The authorizing statute stipulated several other requirements for the demonstration. Section 123(d)(2)(B) of Public Law 110–275, as amended, limited participation in the demonstration to eligible entities in not more than 4 States. Section 123(f)(1) of Public Law 110–275 required the demonstration project to be conducted for a 3-year period. In addition, section 123(g)(1)(B) of Public Law 110–275 required that the demonstration be budget neutral. Specifically, this provision stated that, in conducting the demonstration project, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project under the section were not implemented. Furthermore, section 123(i) of Public Law 110–275 stated that the Secretary may waive such requirements of titles XVIII and XIX of the Act as may be necessary and appropriate for the purpose of carrying out the demonstration project, thus allowing the waiver of Medicare payment rules encompassed in the demonstration.

In January 2014, we released a request for applications (RFA) for the FCHIP demonstration. Using 2013 data from the U.S. Census Bureau, CMS identified Alaska, Montana, Nevada, North Dakota, and Wyoming as meeting the statutory eligibility requirement for participation in the demonstration. The RFA solicited CAHs in these five States to participate in the demonstration, stating that participation would be limited to CAHs in four of the States. To apply, CAHs were required to meet the eligibility requirements in the authorizing legislation, and, in addition, to describe a proposal to enhance health-related services that would complement those currently provided by the CAH and better serve the community's needs. In addition, in the RFA, CMS interpreted the eligible entity definition in the statute as meaning a CAH that receives funding through the MHRFP. The RFA identified four interventions, under which specific waivers of Medicare payment rules would allow for enhanced payment for telehealth, skilled nursing facility/nursing facility beds, ambulance services, and home health services, respectively. These waivers were formulated with the goal of increasing access to care with no net increase in costs.

Ten CAHs were selected for participation in the demonstration, which started on August 1, 2016 and concluded on July 31, 2019. The selected CAHs were located in Montana, Nevada, and North Dakota, and participated in three of the four interventions identified in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38294 through 38296), and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41516 through 41517), and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42044 through 42701). Eight CAHs participated in the telehealth intervention, three CAHs participated in the skilled nursing facility/nursing facility bed intervention, and two CAHs participated in the ambulance services intervention. Each CAH was allowed to participate in more than one of the interventions. None of the selected CAHs were participants in the home health intervention, which was the fourth intervention included in the RFA.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065), we

finalized a policy to address the budget neutrality requirement for the demonstration. We also discussed this policy in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38294 through 38296), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41516 through 41517), and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42044 through 42701), but did not make any changes to the policy that was adopted in FY 2017. As explained in the FY 2017 IPPS/LTCH PPS final rule, we based our selection of CAHs for participation in the demonstration with the goal of maintaining the budget neutrality of the demonstration on its own terms (that is, the demonstration would produce savings from reduced transfers and admissions to other health care providers, thus offsetting any increase in Medicare payments as a result of the demonstration). However, because of the small size of the demonstration and uncertainty associated with the projected Medicare utilization and costs, the policy we adopted in the FY 2017 IPPS/LTCH PPS final rule provides a contingency plan to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met. If analysis of claims data for Medicare beneficiaries receiving services at each of the participating CAHs, as well as from other data sources, including cost reports for these CAHs, shows that increases in Medicare payments under the demonstration during the 3-year period are not sufficiently offset by reductions elsewhere, we will recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide. Because of the small scale of the demonstration, we indicated that we did not believe it would be feasible to implement budget neutrality by reducing payments to only the participating CAHs. Therefore, in the event that this demonstration is found to result in aggregate payments in excess of the amount that would have been paid if this demonstration were not implemented, we will comply with the budget neutrality requirement by reducing payments to all CAHs, not just those participating in the demonstration. We stated that we believe it is appropriate to make any payment reductions across all CAHs because the FCHIP demonstration was specifically designed to test innovations that affect delivery of services by the CAH provider category. We explained our belief that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of Public Law 110–275 permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented, and does not identify the range across which aggregate payments must be held equal.

Based on actuarial analysis using cost report settlements for FYs 2013 and 2014, the FCHIP demonstration is projected to satisfy the budget neutrality requirement and likely yield a total net savings. As we estimated for the FY 2020 IPPS/LTCH PPS final rule, for this FY 2021 IPPS/LTCH PPS proposed rule, we estimate that the total impact of the payment recoupment (if needed) will be no greater than 0.03 percent of CAHs' total Medicare payments (that is, Medicare Part A and Part B) within 1 fiscal year. The final budget neutrality estimates for the FCHIP demonstration will be based on costs incurred during the entire demonstration period, which is August 1, 2016 through July 31, 2019.

b. FCHIP Budget Neutrality Methodology and Analytical Approach

As explained in the FY 2020 IPPS/LTCH PPS final rule, our goal was to maintain the budget neutrality of the demonstration on its own terms (that is, the demonstration would produce savings from reduced transfers and admissions to other health care providers, thus offsetting any increase in payments to the participating CAHs resulting from the demonstration). The budget neutrality assessment will seek to determine if this goal has been met by examining expenditures for beneficiaries who received an intervention-related service(s) at a demonstration CAH or a comparison CAH. The demonstration and comparison groups will be identified as Medicare beneficiaries receiving an intervention-related service (that is, telemedicine, SNF/NF or ambulance) at participating CAHs and non-participating CAHs, respectively. To ensure that there is no cross contamination between the groups, the demonstration and comparison groups will be mutually exclusive so beneficiaries who received intervention-related services at both participating and non-participating CAHs will be included in the demonstration (intervention) group only. The analysis of budget neutrality will seek to identify both the costs related to providing the intervention-related services under the demonstration and any potential downstream effects of these services, including any savings that may have accrued.

We intend to incorporate two components into the budget neutrality analytical approach: (1) Medicare cost reports; and (2) Medicare administrative claims. We propose to estimate the cost of the demonstration for each fiscal year of the demonstration period using Medicare cost reports for the participating hospitals, and Medicare administrative claims and enrollment data for beneficiaries who received demonstration intervention related services.

First, using Medicare administrative claims and enrollment data, a difference-in-difference (DID) regression analysis will be used to compute the impact of the demonstration interventions on Medicare expenditures, relative to what expenditures would have looked like without the demonstration. The DID regression analysis will compare the direct cost and potential downstream effects of intervention services, including any savings that may have accrued, during the baseline and performance period for both the demonstration and comparison groups.

Second, the Medicare administrative claims analysis will be reconciled using data obtained from auditing the participating CAHs' Medicare cost reports. We will estimate the costs of the demonstration using ''as submitted'' cost reports for each hospital's financial fiscal year participation within each demonstration performance year. While the majority of demonstration participants had cost reporting years that aligned with the demonstration period start date of July 1, 2016, several participating CAHs did not have cost reporting years that coincided with the demonstration start date. The cost report is structured to gather costs, revenues and statistical data on the provider's financial fiscal period. As a result, when a CAH's cost reporting year does not align with the timeframes used under the demonstration, additional calculations are necessary to carve-out data that relates to the portion of a cost reporting year when the demonstration was not in effect. We will determine the final budget neutrality results for the demonstration once complete data is available for the demonstration period. While this discussion represents CMS' anticipated approach to assessing the financial impact of the demonstration based on the data available to date, upon receiving data for the full demonstration period, CMS may update and/or modify the FCHIP budget neutrality methodology and analytical approach to ensure that they

appropriately capture the full impact of the demonstration.

Under the policy finalized in the FY 2017 IPPS/LTCH PPS final rule, in the event the demonstration is found not to have been budget neutral, any excess costs will be recouped over a period of 3 cost reporting years. The 3-year period for recoupment will allow for a reasonable timeframe for the payment reduction and minimize any impact on CAHs' operations. Under the policy adopted in FY 2017 IPPS/LTCH PPS final rule, in the event the demonstration is found not to have been budget neutral, any excess costs will be recouped beginning in CY 2020. Based on the currently available data, the determination of budget neutrality results is preliminary and the amount of any reduction to CAH payments that would be needed in order to recoup excess costs under the demonstration remain uncertain. Therefore, we are proposing to revise the policy originally adopted in the FY 2017 IPPS/LTCH PPS final rule, to delay the implementation of any budget neutrality adjustment and will revisit this policy in rulemaking for FY 2022 when we expect to have complete data for the demonstration period. Since our data analysis is incomplete, it is not possible to determine the impact of this policy for any national payment system for FY 2021.

VII. Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2021

A. Background of the LTCH PPS

1. Legislative and Regulatory Authority

Section 123 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), as amended by section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), provides for payment for both the operating and capital-related costs of hospital inpatient stays in long-term care hospitals (LTCHs) under Medicare Part A based on prospectively set rates. The Medicare prospective payment system (PPS) for LTCHs applies to hospitals that are described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act originally defined an LTCH as a hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days. Section 1886(d)(1)(B)(iv)(II) of the Act (''subclause II'' LTCHs) also provided an alternative definition of LTCHs. However, section 15008 of the 21st Century Cures Act (Pub. L. 114–255) amended section 1886 of the Act to exclude former ''subclause II'' LTCHs from being paid under the LTCH PPS and created a new category of IPPS-excluded hospitals, which we refer to as ''extended neoplastic disease care hospitals''), to be paid as hospitals that were formally classified as ''subclause (II)'' LTCHs (82 FR 38298).

Section 123 of the BBRA requires the PPS for LTCHs to be a ''per discharge'' system with a diagnosis-related group (DRG) based patient classification system that reflects the differences in patient resources and costs in LTCHs.

Section 307(b)(1) of the BIPA, among other things, mandates that the Secretary shall examine, and may provide for, adjustments to payments under the LTCH PPS, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment.

In the August 30, 2002 **Federal Register**, we issued a final rule that implemented the LTCH PPS authorized under the BBRA and BIPA (67 FR 55954). For the initial implementation of the LTCH PPS (FYs 2003 through FY 2007), the system used information from LTCH patient records to classify patients into distinct long-term care diagnosis-related groups (LTC–DRGs) based on clinical characteristics and expected resource needs. Beginning in FY 2008, we adopted the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) as the patient classification system used under the LTCH PPS. Payments are calculated for each MS–LTC–DRG and provisions are made for appropriate payment adjustments. Payment rates under the LTCH PPS are updated annually and published in the **Federal Register**.

The LTCH PPS replaced the reasonable cost-based payment system under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) for payments for inpatient services provided by an LTCH with a cost reporting period beginning on or after October 1, 2002. (The regulations implementing the TEFRA reasonable cost-based payment provisions are located at 42 CFR part 413.) With the implementation of the PPS for acute care hospitals authorized by the Social Security Amendments of 1983 (Pub. L. 98–21), which added section 1886(d) to the Act, certain hospitals, including LTCHs, were excluded from the PPS for acute care hospitals and were paid their reasonable costs for inpatient services subject to a per discharge limitation or target amount under the TEFRA system. For each cost reporting period, a hospital-specific ceiling on payments was determined by multiplying the hospital's updated target amount by the number of total current year Medicare discharges. (Generally, in this section of the preamble of this proposed rule, when we refer to discharges, we describe Medicare discharges.) The August 30, 2002 final rule further details the payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002 final rule, we provided for a 5-year transition period from payments under the TEFRA system to payments under the LTCH PPS. During this 5-year transition period, an LTCH's total payment under the PPS was based on an increasing percentage of the Federal rate with a corresponding decrease in the percentage of the LTCH PPS payment that is based on reasonable cost concepts, unless an LTCH made a one-time election to be paid based on 100 percent of the Federal rate. Beginning with LTCHs' cost reporting periods beginning on or after October 1, 2006, total LTCH PPS payments are based on 100 percent of the Federal rate.

In addition, in the August 30, 2002 final rule, we presented an in-depth discussion of the LTCH PPS, including the patient classification system, relative weights, payment rates, additional payments, and the budget neutrality requirements mandated by section 123 of the BBRA. The same final rule that established regulations for the LTCH PPS under 42 CFR part 412, subpart O, also contained LTCH provisions related to covered inpatient services, limitation on charges to beneficiaries, medical review requirements, furnishing of inpatient hospital services directly or under arrangement, and reporting and recordkeeping requirements. We refer readers to the August 30, 2002 final rule for a comprehensive discussion of the research and data that supported the establishment of the LTCH PPS (67 FR 55954).

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623), we implemented the provisions of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67), which mandated the application of the ''site neutral'' payment rate under the LTCH PPS for discharges that do not meet the statutory criteria for exclusion beginning in FY 2016. For cost reporting periods beginning on or after October 1, 2015, discharges that do not meet certain statutory criteria for exclusion

are paid based on the site neutral payment rate. Discharges that do meet the statutory criteria continue to receive payment based on the LTCH PPS standard Federal payment rate. For more information on the statutory requirements of the Pathway for SGR Reform Act of 2013, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57068 through 57075).

In the FY 2018 IPPS/LTCH PPS final rule, we implemented several provisions of the 21st Century Cures Act (''the Cures Act'') (Pub. L. 114–255) that affected the LTCH PPS. (For more information on these provisions, we refer readers to 82 FR 38299.)

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41529), we made conforming changes to our regulations to implement the provisions of section 51005 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), which extends the transitional blended payment rate for site neutral payment rate cases for an additional 2 years. We refer readers to section VII.C. of the preamble of the FY 2019 IPPS/LTCH PPS final rule for a discussion of our final policy. In addition, in the FY 2019 IPPS/LTCH PPS final rule, we removed the 25-percent threshold policy under 42 CFR 412.538.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42439), we further revised our regulations to implement the provisions of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) that relate to the payment adjustment for discharges from LTCHs that do not maintain the requisite discharge payment percentage and the process by which such LTCHs may have the payment adjustment discontinued.

2. Criteria for Classification as an LTCH

a. Classification as an LTCH

Under the regulations at § 412.23(e)(1), to qualify to be paid under the LTCH PPS, a hospital must have a provider agreement with Medicare. Furthermore, § 412.23(e)(2)(i), which implements section 1886(d)(1)(B)(iv) of the Act, requires that a hospital have an average Medicare inpatient length of stay of greater than 25 days to be paid under the LTCH PPS. In accordance with section 1206(a)(3) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67), as amended by section 15007 of Public Law 114–255, we amended our regulations to specify that Medicare Advantage plans' and site neutral payment rate discharges are excluded from the calculation of the average length of stay for all LTCHs, for discharges occurring in cost reporting period beginning on or after October 1, 2015.

b. Hospitals Excluded From the LTCH PPS

The following hospitals are paid under special payment provisions, as described in § 412.22(c) and, therefore, are not subject to the LTCH PPS rules:

- Veterans Administration hospitals.
- Hospitals that are reimbursed under State cost control systems approved under 42 CFR part 403.
- Hospitals that are reimbursed in accordance with demonstration projects authorized under section 402(a) of the Social Security Amendments of 1967 (Pub. L. 90–248) (42 U.S.C. 1395b-1), section 222(a) of the Social Security Amendments of 1972 (Pub. L. 92–603) (42 U.S.C. 1395b–1 (note)) (Statewide all-payer systems, subject to the rate-of-increase test at section 1814(b) of the Act), or section 3201 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) (42 U.S.C. 1315a).
- Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

3. Limitation on Charges to Beneficiaries

In the August 30, 2002 final rule, we presented an in-depth discussion of beneficiary liability under the LTCH PPS (67 FR 55974 through 55975). This discussion was further clarified in the RY 2005 LTCH PPS final rule (69 FR 25676). In keeping with those discussions, if the Medicare payment to the LTCH is the full LTC–DRG payment amount, consistent with other established hospital prospective payment systems, § 412.507 currently provides that an LTCH may not bill a Medicare beneficiary for more than the deductible and coinsurance amounts as specified under §§ 409.82, 409.83, and 409.87, and for items and services specified under § 489.30(a). However, under the LTCH PPS, Medicare will only pay for services furnished during the days for which the beneficiary has coverage until the short-stay outlier (SSO) threshold is exceeded. If the Medicare payment was for a SSO case (in accordance with § 412.529), and that payment was less than the full LTC–DRG payment amount because the beneficiary had insufficient coverage as a result of the remaining Medicare days, the LTCH also is currently permitted to charge the beneficiary for services delivered on those uncovered days (in accordance with § 412.507). In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49623), we amended our regulations to expressly limit the charges that may be imposed upon beneficiaries whose LTCHs' discharges are paid at the site neutral payment rate under the LTCH PPS. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57102), we amended the regulations under § 412.507 to clarify our existing policy that blended payments made to an LTCH during its transitional period (that is, an LTCH's payment for discharges occurring in cost reporting periods beginning in FYs 2016 through 2019) are considered to be site neutral payment rate payments.

B. Proposed Medicare Severity Long-Term Care Diagnosis-Related Group (MS–LTC–DRG) Classifications and Relative Weights for FY 2021

1. Background

Section 123 of the BBRA required that the Secretary implement a PPS for LTCHs to replace the cost-based payment system under TEFRA. Section 307(b)(1) of the BIPA modified the requirements of section 123 of the BBRA by requiring that the Secretary examine the feasibility and the impact of basing payment under the LTCH PPS on the use of existing (or refined) hospital DRGs that have been modified to account for different resource use of LTCH patients.

When the LTCH PPS was implemented for cost reporting periods beginning on or after October 1, 2002, we adopted the same DRG patient classification system utilized at that time under the IPPS. As a component of the LTCH PPS, we refer to this patient classification system as the ''long-term care diagnosis-related groups (LTC–DRGs).'' Although the patient classification system used under both the LTCH PPS and the IPPS are the same, the relative weights are different. The established relative weight methodology and data used under the LTCH PPS result in relative weights under the LTCH PPS that reflect the differences in patient resource use of LTCH patients, consistent with section 123(a)(1) of the BBRA (Pub. L. 106–113).

As part of our efforts to better recognize severity of illness among patients, in the FY 2008 IPPS final rule with comment period (72 FR 47130), the MS–DRGs and the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) were adopted under the IPPS and the LTCH PPS, respectively, effective beginning October 1, 2007 (FY 2008). For a full description of the development, implementation, and rationale for the use of the MS–DRGs and MS–LTC–DRGs, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47141 through 47175 and 47277 through 47299). (We note that, in that

same final rule, we revised the regulations at § 412.503 to specify that for LTCH discharges occurring on or after October 1, 2007, when applying the provisions of 42 CFR part 412, subpart O applicable to LTCHs for policy descriptions and payment calculations, all references to LTC–DRGs would be considered a reference to MS–LTC–DRGs. For the remainder of this section, we present the discussion in terms of the current MS–LTC–DRG patient classification system unless specifically referring to the previous LTC–DRG patient classification system that was in effect before October 1, 2007.)

The MS–DRGs adopted in FY 2008 represent an increase in the number of DRGs by 207 (that is, from 538 to 745) (72 FR 47171). The MS–DRG classifications are updated annually. There are currently 761 MS–DRG groupings. For FY 2021, there would be 767 MS–DRG groupings based on the proposed changes, as discussed in section II.E. of the preamble of this proposed rule. Consistent with section 123 of the BBRA, as amended by section 307(b)(1) of the BIPA, and § 412.515 of the regulations, we use information derived from LTCH PPS patient records to classify LTCH discharges into distinct MS–LTC–DRGs based on clinical characteristics and estimated resource needs. Then we assign an appropriate weight to the MS–LTC–DRGs to account for the difference in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCHs.

In this section of this proposed rule, we provide a general summary of our existing methodology for determining the FY 2021 MS–LTC–DRG relative weights under the LTCH PPS.

In this proposed rule, in general, for FY 2021, we are proposing to continue to use our existing methodology to determine the MS–LTC–DRG relative weights (as discussed in greater detail in section VII.B.3. of the preamble of this proposed rule). As we established when we implemented the dual rate LTCH PPS payment structure codified under § 412.522, which began in FY 2016, we are proposing that the annual recalibration of the MS–LTC–DRG relative weights are determined: (1) Using only data from available LTCH PPS claims that would have qualified for payment under the new LTCH PPS standard Federal payment rate if that rate had been in effect at the time of discharge when claims data from time periods before the dual rate LTCH PPS payment structure applies are used to calculate the relative weights; and (2) using only data from available LTCH PPS claims that qualify for payment under the new LTCH PPS standard Federal payment rate when claims data from time periods after the dual rate LTCH PPS payment structure applies are used to calculate the relative weights (80 FR 49624). That is, under our current methodology, our MS–LTC–DRG relative weight calculations do not use data from cases paid at the site neutral payment rate under § 412.522(c)(1) or data from cases that would have been paid at the site neutral payment rate if the dual rate LTCH PPS payment structure had been in effect at the time of that discharge. For the remainder of this discussion, we use the phrase ''applicable LTCH cases'' or ''applicable LTCH data'' when referring to the resulting claims data set used to calculate the relative weights (as described later in greater detail in section VII.B.3.c. of the preamble of this proposed rule). In addition, for FY 2021, we are proposing to continue to exclude the data from all-inclusive rate providers and LTCHs paid in accordance with demonstration projects, as well as any Medicare Advantage claims from the MS–LTC–DRG relative weight calculations for the reasons discussed in section VII.B.3.c. of the preamble of this proposed rule.

Furthermore, for FY 2021, in using data from applicable LTCH cases to establish MS–LTC–DRG relative weights, we are proposing to continue to establish low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs with less than 25 cases) using our quintile methodology in determining the MS–LTC–DRG relative weights because LTCHs do not typically treat the full range of diagnoses as do acute care hospitals. Therefore, for purposes of determining the relative weights for the large number of low-volume MS–LTC–DRGs, we grouped all of the low-volume MS–LTC–DRGs into five quintiles based on average charges per discharge. Then, under our existing methodology, we accounted for adjustments made to LTCH PPS standard Federal payments for short-stay outlier (SSO) cases (that is, cases where the covered length of stay at the LTCH is less than or equal to five-sixths of the geometric average length of stay for the MS–LTC–DRG), and we made adjustments to account for nonmonotonically increasing weights, when necessary. The methodology is premised on more severe cases under the MS–LTC–DRG system requiring greater expenditure of medical care resources and higher average charges such that, in the severity levels within a base MS–LTC–DRG, the relative weights should increase monotonically with severity from the lowest to highest severity level. (We discuss each of these components of our MS–LTC–DRG relative weight methodology in greater detail in section VII.B.3.g. of the preamble of this proposed rule.)

2. Patient Classifications Into MS–LTC–DRGs

a. Background

The MS–DRGs (used under the IPPS) and the MS–LTC–DRGs (used under the LTCH PPS) are based on the CMS DRG structure. As noted previously in this section, we refer to the DRGs under the LTCH PPS as MS–LTC–DRGs although they are structurally identical to the MS–DRGs used under the IPPS.

The MS–DRGs are organized into 25 major diagnostic categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as MDC 22, Burns). Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are assigned based on a surgical hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. The GROUPER software program does not recognize all ICD–10–PCS procedure codes as procedures affecting DRG assignment. That is, procedures that are not surgical (for example, EKGs), or minor surgical procedures (for example, a biopsy of skin and subcutaneous tissue (procedure code 0JBH3ZX)) do not affect the MS–LTC–DRG assignment based on their presence on the claim.

Generally, under the LTCH PPS, a Medicare payment is made at a predetermined specific rate for each discharge that varies based on the MS–LTC–DRG to which a beneficiary's discharge is assigned. Cases are classified into MS–LTC–DRGs for payment based on the following six data elements:

- Principal diagnosis.
- Additional or secondary diagnoses.
- Surgical procedures.
- Age.
- Sex.
- Discharge status of the patient.

Currently, for claims submitted using version ASC X12 5010 format, up to 25 diagnosis codes and 25 procedure codes are considered for an MS–DRG assignment. This includes one principal diagnosis and up to 24 secondary diagnoses for severity of illness determinations. (For additional information on the processing of up to 25 diagnosis codes and 25 procedure codes on hospital inpatient claims, we refer readers to section II.G.11.c. of the preamble of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127).)

Under the HIPAA transactions and code sets regulations at 45 CFR parts 160 and 162, covered entities must comply with the adopted transaction standards and operating rules specified in subparts I through S of part 162. Among other requirements, on or after January 1, 2012, covered entities were required to use the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X233A1 for the health care claims or equivalent encounter information transaction (45 CFR 162.1102(c)).

HIPAA requires covered entities to use the applicable medical data code set requirements when conducting HIPAA transactions (45 CFR 162.1000). Currently, upon the discharge of the patient, the LTCH must assign appropriate diagnosis and procedure codes from the most current version of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, both of which were required to be implemented October 1, 2015 (45 CFR 162.1002(c)(2) and (3)). For additional information on the implementation of the ICD–10 coding system, we refer readers to section II.F.1. of the preamble of the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787 through 56790) and section II.E.1. of the preamble of this proposed rule. Additional coding instructions and examples are published in the AHA's *Coding Clinic for ICD–10–CM/PCS.*

To create the MS–DRGs (and by extension, the MS–LTC–DRGs), base DRGs were subdivided according to the presence of specific secondary diagnoses designated as complications or comorbidities (CCs) into one, two, or three levels of severity, depending on the impact of the CCs on resources used for those cases. Specifically, there are sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or a major complication or comorbidity (MCC). We refer readers to section II.D. of the preamble of the FY 2008 IPPS final rule with comment period for a detailed discussion about the creation of MS–DRGs based on severity of illness levels (72 FR 47141 through 47175).

MACs enter the clinical and demographic information submitted by LTCHs into their claims processing systems and subject this information to a series of automated screening processes called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before assignment into a MS–LTC–DRG can be made. During this process, certain cases are selected for further explanation (74 FR 43949).

After screening through the MCE, each claim is classified into the appropriate MS–LTC–DRG by the Medicare LTCH GROUPER software on the basis of diagnosis and procedure codes and other demographic information (age, sex, and discharge status). The GROUPER software used under the LTCH PPS is the same GROUPER software program used under the IPPS. Following the MS–LTC–DRG assignment, the MAC determines the prospective payment amount by using the Medicare PRICER program, which accounts for hospital-specific adjustments. Under the LTCH PPS, we provide an opportunity for LTCHs to review the MS–LTC–DRG assignments made by the MAC and to submit additional information within a specified timeframe as provided in § 412.513(c).

The GROUPER software is used both to classify past cases to measure relative hospital resource consumption to establish the MS–LTC–DRG relative weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible MS–DRG and MS–LTC–DRG classification changes and to recalibrate the MS–DRG and MS–LTC–DRG relative weights during our annual update under both the IPPS (§ 412.60(e)) and the LTCH PPS (§ 412.517), respectively.

b. Proposed Changes to the MS–LTC–DRGs for FY 2021

As specified by our regulations at § 412.517(a), which require that the MS–LTC–DRG classifications and relative weights be updated annually, and consistent with our historical practice of using the same patient classification system under the LTCH PPS as is used under the IPPS, in this proposed rule, we are proposing to update the MS–LTC–DRG classifications effective October 1, 2020 through September 30, 2021 (FY 2021), consistent with the proposed changes to specific MS–DRG classifications presented in section II.F. of the preamble of this proposed rule. Accordingly, the proposed MS–LTC–DRGs for FY 2021 presented in section II.F. of the preamble of this proposed rule are the same as the MS–DRGs that are being used under the IPPS for FY 2021. In addition, because the proposed MS–LTC–DRGs for FY 2021 are the same as the proposed MS–DRGs for FY 2021, the other proposed changes that affect MS–DRG (and by extension MS–LTC–DRG) assignments under proposed GROUPER Version 38 as discussed in section II.E. of the preamble of this proposed rule, including the proposed changes to the MCE software and the ICD–10–CM/PCS coding system, also are applicable under the LTCH PPS for FY 2021.

3. Development of the Proposed FY 2021 MS–LTC–DRG Relative Weights

a. General Overview of the Development of the MS–LTC–DRG Relative Weights

One of the primary goals for the implementation of the LTCH PPS is to pay each LTCH an appropriate amount for the efficient delivery of medical care to Medicare patients. The system must be able to account adequately for each LTCH's case-mix in order to ensure both fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is costlier (67 FR 55984). To accomplish these goals, we have annually adjusted the LTCH PPS standard Federal prospective payment rate by the applicable relative weight in determining payment to LTCHs for each case. In order to make these annual adjustments under the dual rate LTCH PPS payment structure, beginning with FY 2016, we recalibrate the MS–LTC–DRG relative weighting factors annually using data from applicable LTCH cases (80 FR 49614 through 49617). Under this policy, the resulting MS–LTC–DRG relative weights would continue to be used to adjust the LTCH PPS standard Federal payment rate when calculating the payment for LTCH PPS standard Federal payment rate cases.

The established methodology to develop the MS–LTC–DRG relative weights is generally consistent with the methodology established when the LTCH PPS was implemented in the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55991). However, there have been some modifications of our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity resulting from the adoption of the MS–LTC–DRGs, along with the change made in conjunction with the implementation of the dual rate LTCH PPS payment structure beginning in FY 2016 to use LTCH claims data from only LTCH PPS

standard Federal payment rate cases (or LTCH PPS cases that would have qualified for payment under the LTCH PPS standard Federal payment rate if the dual rate LTCH PPS payment structure had been in effect at the time of the discharge). (For details on the modifications to our historical procedures for assigning relative weights in cases of zero volume and/or nonmonotonicity, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47289 through 47295) and the FY 2009 IPPS final rule (73 FR 48542 through 48550).) For details on the change in our historical methodology to use LTCH claims data only from LTCH PPS standard Federal payment rate cases (or cases that would have qualified for such payment had the LTCH PPS dual payment rate structure been in effect at the time) to determine the MS–LTC–DRG relative weights, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49614 through 49617). Under the LTCH PPS, relative weights for each MS–LTC–DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups (§ 412.515). To ensure that Medicare patients classified to each MS–LTC–DRG have access to an appropriate level of services and to encourage efficiency, we calculate a relative weight for each MS–LTC–DRG that represents the resources needed by an average inpatient LTCH case in that MS–LTC–DRG. For example, cases in an MS–LTC–DRG with a relative weight of 2 would, on average, cost twice as much to treat as cases in an MS–LTC–DRG with a relative weight of 1.

b. Development of the Proposed MS–LTC–DRG Relative Weights for FY 2021

In this proposed rule, we are proposing to continue to use our current methodology to determine the MS–LTC–DRG relative weights for FY 2021, including the continued application of established policies related to: The hospital-specific relative value methodology, the treatment of severity levels in the MS–LTC–DRGs, low-volume and no-volume MS–LTC–DRGs, adjustments for nonmonotonicity, the steps for calculating the MS–LTC–DRG relative weights with a budget neutrality factor, and only using data from applicable LTCH cases (which includes our policy of only using cases that would meet the criteria for exclusion from the site neutral payment rate (or, for discharges occurring prior to the implementation of the dual rate LTCH PPS payment structure, would have met the criteria for exclusion had those criteria been in effect at the time of the discharge)).

In this section, we present our proposed application of our existing methodology for determining the proposed MS–LTC–DRG relative weights for FY 2021, and we discuss the effects of our proposals concerning the data used to determine the FY 2021 MS–LTC–DRG relative weights on the various components of our existing methodology in the discussion that follows.

We generally provide the low-volume quintiles and no-volume crosswalk data previously published in Tables 13A and 13B for each annual proposed and final rule as one of our supplemental IPPS/LTCH PPS related data files that are made available for public use via the internet on the CMS website for the respective rule and fiscal year (that is, FY 2019 and subsequent fiscal years) at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* to streamline the information made available to the public that is used in the annual development of IPPS Table 11 and to make it easier for the public to navigate and find the relevant data and information used for the development of proposed and final payment rates or factors for the applicable payment year while continuing to furnish the same information the tables provided in previous fiscal years (83 FR 41522). We refer readers to the CMS website for the low-volume quintiles and no-volume crosswalk data previously furnished via Tables 13A and 13B.

c. Data

For this FY 2021 IPPS/LTCH PPS proposed rule, consistent with our proposals regarding the calculation of the proposed MS–LTC–DRG relative weights for FY 2021, we obtained total charges from FY 2019 Medicare LTCH claims data from the December 2019 update of the FY 2019 MedPAR file, which are the best available data at this time, and we are proposing to use Version 38 of the GROUPER to classify LTCH cases. Consistent with our historical practice, we are proposing that if more recent data become available, we would use those data and the finalized Version 38 of the GROUPER in establishing the FY 2021 MS–LTC–DRG relative weights in the final rule.

To calculate the proposed FY 2021 MS–LTC–DRG relative weights under the dual rate LTCH PPS payment structure, we are proposing to continue to use applicable LTCH data, which includes our policy of only using cases that meet the criteria for exclusion from the site neutral payment rate (or would have met the criteria had they been in effect at the time of the discharge) (80 FR 49624). Specifically, we began by first evaluating the LTCH claims data in the December 2019 update of the FY 2019 MedPAR file to determine which LTCH cases would meet the criteria for exclusion from the site neutral payment rate under § 412.522(b) or had the dual rate LTCH PPS payment structure applied to those cases at the time of discharge. We identified the FY 2019 LTCH cases that were not assigned to MS–LTC–DRGs 876, 880, 881, 882, 883, 884, 885, 886, 887, 894, 895, 896, 897, 945, and 946, which identify LTCH cases that do not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation; and that either—

- The admission to the LTCH was ''immediately preceded'' by discharge from a subsection (d) hospital and the immediately preceding stay in that subsection (d) hospital included at least 3 days in an ICU, as we define under the ICU criterion; or
- The admission to the LTCH was ''immediately preceded'' by discharge from a subsection (d) hospital and the claim for the LTCH discharge includes the applicable procedure code that indicates at least 96 hours of ventilator services were provided during the LTCH stay, as we define under the ventilator criterion. Claims data from the FY 2019 MedPAR file that reported ICD–10–PCS procedure code 5A1955Z were used to identify cases involving at least 96 hours of ventilator services in accordance with the ventilator criterion. (We note that, for purposes of developing the MS–LTC–DRG relative weights we have previously addressed the treatment of cases that would have been excluded from the site neutral payment rate under the statutory provisions that provided for temporary exception from the site neutral payment rate under the LTCH PPS for certain spinal cord specialty hospitals or for certain severe wound care discharges from certain LTCHs provided by sections 15009 and 15010 of Public Law 114–255, respectively. The temporary exception from the site neutral payment rate for certain spinal cord specialty hospitals is effective for discharges in cost reporting periods beginning during FYs 2018 and 2019, and the temporary exception from the site neutral payment rate for certain severe wound care discharges from certain LTCHs was effective for a discharge in cost reporting period beginning during FY 2018. These statutory provisions will no longer be in effective for any discharges

occurring in FY 2021 (that is, an LTCH with a cost reporting period that begins on the last day of FY 2019, on September 30, 2019, would end on September 29, 2020, the day prior to the start of FY 2021 on October 1, 2020). Therefore, we no longer need to address the treatment of these cases for purposes of developing the MS–LTC–DRG relative weights for FY 2021 and subsequent years.)

Furthermore, consistent with our historical methodology, we excluded any claims in the resulting data set that were submitted by LTCHs that were all-inclusive rate providers and LTCHs that are paid in accordance with demonstration projects authorized under section 402(a) of Public Law 90–248 or section 222(a) of Public Law 92–603. In addition, consistent with our historical practice and our policies, we excluded any Medicare Advantage (Part C) claims in the resulting data. Such claims were identified based on the presence of a GHO Paid indicator value of ''1'' in the MedPAR files. The claims that remained after these three trims (that is, the applicable LTCH data) were then used to calculate the MS–LTC–DRG relative weights for FY 2021.

In summary, in general, we identified the claims data used in the development of the proposed FY 2021 MS–LTC–DRG relative weights in this proposed rule, by trimming claims data that were paid the site neutral payment rate or would have been paid the site neutral payment rate had the dual payment rate structure been in effect. Finally, we propose to trim the claims data of all-inclusive rate providers reported in the December 2019 update of the FY 2019 MedPAR file and any Medicare Advantage claims data. There were no data from any LTCHs that are paid in accordance with a demonstration project reported in the December 2019 update of the FY 2019 MedPAR file, but, had there been any, we would have trimmed the claims data from those LTCHs as well, in accordance with our established policy. We are proposing to use the remaining data (that is, the applicable LTCH data) to calculate the relative weights for FY 2021.

d. Hospital-Specific Relative Value (HSRV) Methodology

By nature, LTCHs often specialize in certain areas, such as ventilator-dependent patients. Some case types (MS–LTC–DRGs) may be treated, to a large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. This nonrandom distribution of cases with relatively high (or low) charges in specific MS–LTC–DRGs has the potential to inappropriately distort the measure of average charges. To account for the fact that cases may not be randomly distributed across LTCHs, consistent with the methodology we have used since the implementation of the LTCH PPS, in this FY 2021 IPPS/LTCH PPS proposed rule, we are proposing to continue to use a hospital-specific relative value (HSRV) methodology to calculate the MS–LTC–DRG relative weights for FY 2021. We believe that this method removes this hospital-specific source of bias in measuring LTCH average charges (67 FR 55985). Specifically, under this methodology, we reduce the impact of the variation in charges across providers on any particular MS–LTC–DRG relative weight by converting each LTCH's charge for an applicable LTCH case to a relative value based on that LTCH's average charge for such cases.

Under the HSRV methodology, we standardize charges for each LTCH by converting its charges for each applicable LTCH case to hospital-specific relative charge values and then adjusting those values for the LTCH's case-mix. The adjustment for case-mix is needed to rescale the hospital-specific relative charge values (which, by definition, average 1.0 for each LTCH). The average relative weight for an LTCH is its case-mix; therefore, it is reasonable to scale each LTCH's average relative charge value by its case-mix. In this way, each LTCH's relative charge value is adjusted by its case-mix to an average that reflects the complexity of the applicable LTCH cases it treats relative to the complexity of the applicable LTCH cases treated by all other LTCHs (the average LTCH PPS case-mix of all applicable LTCH cases across all LTCHs).

In accordance with our established methodology, for FY 2021, we are proposing to continue to standardize charges for each applicable LTCH case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described in section VII.B.3.g. of the preamble of this proposed rule (Step 3) of the preamble of this proposed rule) by the average adjusted charge for all applicable LTCH cases at the LTCH in which the case was treated. SSO cases are cases with a length of stay that is less than or equal to five-sixths the average length of stay of the MS–LTC–DRG (§§ 412.529 and 412.503). The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The resulting ratio was multiplied by that LTCH's case-mix index to determine the standardized charge for the case.

Multiplying the resulting ratio by the LTCH's case-mix index accounts for the fact that the same relative charges are given greater weight at an LTCH with higher average costs than they would at an LTCH with low average costs, which is needed to adjust each LTCH's relative charge value to reflect its case-mix relative to the average case-mix for all LTCHs. By standardizing charges in this manner, we count charges for a Medicare patient at an LTCH with high average charges as less resource intensive than they would be at an LTCH with low average charges. For example, a $10,000 charge for a case at an LTCH with an average adjusted charge of $17,500 reflects a higher level of relative resource use than a $10,000 charge for a case at an LTCH with the same case-mix, but an average adjusted charge of $35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

e. Treatment of Severity Levels in Developing the Proposed MS–LTC–DRG Relative Weights

For purposes of determining the MS–LTC–DRG relative weights, under our historical methodology, there are three different categories of MS–DRGs based on volume of cases within specific MS–LTC–DRGs: (1) MS–LTC–DRGs with at least 25 applicable LTCH cases in the data used to calculate the relative weight, which are each assigned a unique relative weight; (2) low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases that are grouped into quintiles (as described later in this section of this proposed rule) and assigned the relative weight of the quintile); and (3) no-volume MS–LTC–DRGs that are cross-walked to other MS–LTC–DRGs based on the clinical similarities and assigned the relative weight of the cross-walked MS–LTC–DRG (as described in greater detail in this proposed rule). For FY 2021, we are proposing to continue to use applicable LTCH cases to establish the same volume-based categories to calculate the FY 2021 MS–LTC–DRG relative weights.

In determining the proposed FY 2021 MS–LTC–DRG relative weights, when necessary, as is our longstanding practice, we are proposing to make adjustments to account for nonmonotonicity, as discussed in greater detail later in Step 6 of section VII.B.3.g. of the preamble of this

proposed rule. We refer readers to the discussion in the FY 2010 IPPS/RY 2010 LTCH PPS final rule for our rationale for including an adjustment for nonmonotonicity (74 FR 43953 through 43954).

f. Proposed Low-Volume MS–LTC–DRGs

In order to account for proposed MS–LTC–DRGs with low-volume (that is, with fewer than 25 applicable LTCH cases), consistent with our existing methodology, we are proposing to continue to employ the quintile methodology for low-volume MS–LTC–DRGs, such that we grouped the ''low-volume MS–LTC–DRGs'' (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases into one of five categories (quintiles) based on average charges (67 FR 55984 through 55995; 72 FR 47283 through 47288; and 81 FR 25148).) In cases where the initial assignment of a low-volume MS–LTC–DRG to a quintile results in nonmonotonicity within a base-DRG, we are proposing to make adjustments to the resulting low-volume MS–LTC–DRGs to preserve monotonicity, as discussed in detail in section VII.B.3.g. (Step 6) of the preamble of this proposed rule.

In this proposed rule, based on the best available data (that is, the December 2019 update of the FY 2019 MedPAR files), we identified 252 MS–LTC–DRGs that contained between 1 and 24 applicable LTCH cases. This list of MS–LTC–DRGs was then divided into 1 of the 5 low-volume quintiles, each containing at least 50 MS–LTC–DRGs (252/5 = 50 with a remainder of 2). We assigned the low-volume MS–LTC–DRGs to specific low-volume quintiles by sorting the low-volume MS–LTC–DRGs in ascending order by average charge in accordance with our established methodology. Based on the data available for this proposed rule, the number of proposed MS–LTC–DRGs with less than 25 applicable LTCH cases was not evenly divisible by 5 and, therefore, we are proposing to employ our historical methodology for determining which of the low-volume quintiles would contain the additional low-volume MS–LTC–DRG. Specifically for this proposed rule, after organizing the proposed MS–LTC–DRGs by ascending order by average charge, we assigned the first 50 (1st through 50th) of proposed low-volume MS–LTC–DRGs (with the lowest average charge) into Quintile 1. Because the average charge of the 51 low-volume MS–LTC–DRG in the sorted list was closer to the average charge of the 50 low-volume MS–LTC–DRG (assigned to Quintile 1) than to the average charge of the 52 low-volume MS–LTC–DRG (assigned to Quintile 2), we assigned it to Quintile 1 (such that Quintile 1 contains 51 low-volume MS–LTC–DRGs before any adjustments for nonmonotonicity, as discussed in this proposed rule). The 50 MS–LTC–DRGs with the highest average charge were assigned into Quintile 5. Because the average charge of the 202nd low-volume MS–LTC–DRG in the sorted list was closer to the average charge of the 203rd low-volume MS–LTC–DRG (assigned to Quintile 5) than to the average charge of the 201st low-volume MS–LTC–DRG (assigned to Quintile 4), we assigned it to Quintile 5 (such that Quintile 5 contains 51 low-volume MS–LTC–DRGs before any adjustments for nonmonotonicity, as discussed in this proposed rule). This resulted in 3 of the 5 low-volume quintiles containing 50 MS–LTC–DRGs (Quintiles 2 through 4) and 2 low-volume quintiles containing 51 MS–LTC–DRGs (Quintiles 1 and 5). As discussed earlier, for this proposed rule, we are providing the list of the composition of the proposed low-volume quintiles for proposed low-volume MS–LTC–DRGs for FY 2021 in a supplemental data file for public use posted via the internet on the CMS website for this proposed rule at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* in order to streamline the information made available to the public that is used in the annual development of Table 11.

In order to determine the proposed FY 2021 relative weights for the proposed low-volume MS–LTC–DRGs, consistent with our historical practice, we are proposing to use the five low-volume quintiles described previously. We determined a proposed relative weight and (geometric) average length of stay for each of the five proposed low-volume quintiles using the methodology described in section VII.B.3.g. of the preamble of this proposed rule. We are proposing to assign the same proposed relative weight and average length of stay to each of the proposed low-volume MS–LTC–DRGs that make up an individual low-volume quintile. We note that, as this system is dynamic, it is possible that the number and specific type of MS–LTC–DRGs with a low-volume of applicable LTCH cases will vary in the future. Furthermore, we note that we continue to monitor the volume (that is, the number of applicable LTCH cases) in the low-volume quintiles to ensure that our quintile assignments used in determining the MS–LTC–DRG relative weights result in appropriate payment for LTCH cases grouped to proposed low-volume MS–LTC–DRGs and do not result in an unintended financial incentive for LTCHs to inappropriately admit these types of cases.

g. Steps for Determining the Proposed FY 2021 MS–LTC–DRG Relative Weights

In this proposed rule, we are proposing to continue to use our current methodology to determine the proposed FY 2021 MS–LTC–DRG relative weights.

In summary, to determine the proposed FY 2021 MS–LTC–DRG relative weights, we are proposing to group applicable LTCH cases to the appropriate proposed MS–LTC–DRG, while taking into account the proposed low-volume quintiles (as described previously) and cross-walked proposed no-volume MS–LTC–DRGs (as described later in this section). After establishing the appropriate proposed MS–LTC–DRG (or proposed low-volume quintile), we are proposing to calculate the proposed FY 2021 relative weights by first removing cases with a length of stay of 7 days or less and statistical outliers (Steps 1 and 2). Next, we are proposing to adjust the number of applicable LTCH cases in each proposed MS–LTC–DRG (or proposed low-volume quintile) for the effect of SSO cases (Step 3). After removing applicable LTCH cases with a length of stay of 7 days or less (Step 1) and statistical outliers (Step 2), which are the SSO-adjusted applicable LTCH cases and corresponding charges (Step 3), we are proposing to calculate proposed ''relative adjusted weights'' for each proposed MS–LTC–DRG (or proposed low-volume quintile) using the HSRV method.

Step 1—Remove cases with a length of stay of 7 days or less.

The first step in our proposed calculation of the proposed FY 2021 MS–LTC–DRG relative weights is to remove cases with a length of stay of 7 days or less. The MS–LTC–DRG relative weights reflect the average of resources used on representative cases of a specific type. Generally, cases with a length of stay of 7 days or less do not belong in an LTCH because these stays do not fully receive or benefit from treatment that is typical in an LTCH stay, and full resources are often not used in the earlier stages of admission to an LTCH. If we were to include stays of 7 days or less in the computation of the FY 2021 MS–LTC–DRG relative weights, the value of many relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate. We do not believe that it would be appropriate to compromise the integrity of the

payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at an LTCH by including data from these very short stays. Therefore, consistent with our existing relative weight methodology, in determining the proposed FY 2021 MS–LTC–DRG relative weights, we are proposing to remove LTCH cases with a length of stay of 7 days or less from applicable LTCH cases. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 2—Remove statistical outliers.

The next step in our proposed calculation of the proposed FY 2021 MS–LTC–DRG relative weights is to remove statistical outlier cases from the LTCH cases with a length of stay of at least 8 days. Consistent with our existing relative weight methodology, we are proposing to continue to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each MS–LTC–DRG. These statistical outliers are removed prior to calculating the proposed relative weights because we believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the proposed relative weights could result in an inaccurate relative weight that does not truly reflect relative resource use among those MS–LTC–DRGs. (For additional information on what is removed in this step of the proposed relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.) After removing cases with a length of stay of 7 days or less and statistical outliers, we were left with applicable LTCH cases that have a length of stay greater than or equal to 8 days. In this proposed rule, we refer to these cases as ''trimmed applicable LTCH cases.''

Step 3—Adjust charges for the effects of SSOs.

As the next step in the calculation of the proposed FY 2021 MS–LTC–DRG relative weights, consistent with our historical approach, we are proposing to adjust each LTCH's charges per discharge for those remaining cases (that is, trimmed applicable LTCH cases) for the effects of SSOs (as defined in § 412.529(a) in conjunction with § 412.503). Specifically, we are proposing to make this adjustment by counting an SSO case as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay for the MS–LTC–DRG for non-SSO cases. This has the effect of proportionately reducing the impact of the lower charges for the SSO cases in calculating the average charge for the MS–LTC–DRG. This process produces the same result as if the actual charges per discharge of an SSO case were adjusted to what they would have been had the patient's length of stay been equal to the average length of stay of the MS–LTC–DRG.

Counting SSO cases as full LTCH cases with no adjustment in determining the proposed FY 2021 MS–LTC–DRG relative weights would lower the proposed FY 2021 MS–LTC–DRG relative weight for affected MS–LTC–DRGs because the relatively lower charges of the SSO cases would bring down the average charge for all cases within a MS–LTC–DRG. This would result in an ''underpayment'' for non-SSO cases and an ''overpayment'' for SSO cases. Therefore, we are proposing to continue to adjust for SSO cases under § 412.529 in this manner because it would result in more appropriate payments for all LTCH PPS standard Federal payment rate cases. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 4—Calculate the proposed FY 2021 MS–LTC–DRG relative weights on an iterative basis.

Consistent with our historical relative weight methodology, we are proposing to calculate the proposed FY 2021 MS–LTC–DRG relative weights using the HSRV methodology, which is an iterative process. First, for each SSO-adjusted trimmed applicable LTCH case, we calculated a hospital-specific relative charge value by dividing the charge per discharge after adjusting for SSOs of the LTCH case (from Step 3) by the average charge per SSO-adjusted discharge for the LTCH in which the case occurred. The resulting ratio is then multiplied by the LTCH's case-mix index to produce an adjusted hospital-specific relative charge value for the case. We used an initial case-mix index value of 1.0 for each LTCH.

For each proposed MS–LTC–DRG, we calculated the proposed FY 2021 relative weight by dividing the SSO-adjusted average of the hospital-specific relative charge values for applicable LTCH cases for the proposed MS–LTC–DRG (that is, the sum of the hospital-specific relative charge value from above divided by the sum of equivalent cases from Step 3 for each proposed MS–LTC–DRG) by the overall SSO-adjusted average hospital-specific relative charge value across all applicable LTCH cases for all LTCHs (that is, the sum of the hospital-specific relative charge value from above divided by the sum of equivalent applicable LTCH cases from Step 3 for each proposed MS–LTC–DRG). Using these recalculated MS–LTC–DRG relative weights, each LTCH's average relative weight for all of its SSO-adjusted trimmed applicable LTCH cases (that is, its case-mix) was calculated by dividing the sum of all the LTCH's MS–LTC–DRG relative weights by its total number of SSO-adjusted trimmed applicable LTCH cases. The LTCHs' hospital-specific relative charge values (from previous) are then multiplied by the hospital-specific case-mix indexes. The hospital-specific case-mix adjusted relative charge values are then used to calculate a new set of proposed MS–LTC–DRG relative weights across all LTCHs. This iterative process continued until there was convergence between the relative weights produced at adjacent steps, for example, when the maximum difference was less than 0.0001.

Step 5—Determine a proposed FY 2021 relative weight for MS–LTC–DRGs with no applicable LTCH cases.

Using the trimmed applicable LTCH cases, consistent with our historical methodology, we identified the proposed MS–LTC–DRGs for which there were no claims in the December 2019 update of the FY 2019 MedPAR file and, therefore, for which no charge data was available for these MS–LTC–DRGs. Because patients with a number of the diagnoses under these MS–LTC–DRGs may be treated at LTCHs, consistent with our historical methodology, we generally assign a relative weight to each of the no-volume MS–LTC–DRGs based on clinical similarity and relative costliness (with the exception of ''transplant'' MS–LTC–DRGs, ''error'' MS–LTC–DRGs, and MS–LTC–DRGs that indicate a principal diagnosis related to a psychiatric diagnosis or rehabilitation (referred to as the ''psychiatric or rehabilitation'' MS–LTC–DRGs), as discussed later in this section of this proposed rule). (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55991 and 74 FR 43959 through 43960.)

Consistent with our existing methodology, we are proposing to crosswalk each no-volume proposed MS–LTC–DRG to another proposed MS–LTC–DRG for which we calculated a proposed relative weight (determined in accordance with the methodology as previously described). Then, the ''no-volume'' proposed MS–LTC–DRG is assigned the same proposed relative weight (and average length of stay) of

the proposed MS–LTC–DRG to which it was cross-walked (as described in greater detail in this section of this proposed rule).

Of the 767 proposed MS–LTC–DRGs for FY 2021, we identified 375 MS–LTC–DRGs for which there were no trimmed applicable LTCH cases. This number includes the 11 ''transplant'' MS–LTC–DRGs, the 2 ''error'' MS–LTC–DRGs, and the 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs, which are discussed in this section of this rule, such that we identified 347 MS–LTC–DRGs that for which we would propose to assign a relative weight using our existing ''no-volume'' proposed MS–LTC–DRG methodology (that is, 375 − 11 − 2 − 15 = 347). We are proposing to assign proposed relative weights to each of the 347 no-volume proposed MS–LTC–DRGs based on clinical similarity and relative costliness to 1 of the remaining 392 (767 − 375 = 392) proposed MS–LTC–DRGs for which we calculated proposed relative weights based on the trimmed applicable LTCH cases in the FY 2019 MedPAR file data using the steps described previously. (For the remainder of this discussion, we refer to the ''cross-walked'' proposed MS–LTC–DRGs as one of the 392 proposed MS–LTC–DRGs to which we cross-walked each of the 347 ''no-volume'' proposed MS–LTC–DRGs.) Then, we are generally proposing to assign the 347 no-volume proposed MS–LTC–DRGs the proposed relative weight of the cross-walked proposed MS–LTC–DRG. (As explained in Step 6, when necessary, we made adjustments to account for nonmonotonicity.)

We cross-walked the no-volume proposed MS–LTC–DRG to a proposed MS–LTC–DRG for which we calculated proposed relative weights based on the December 2019 update of the FY 2019 MedPAR file, and to which it is similar clinically in intensity of use of resources and relative costliness as determined by criteria such as care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, postoperative care, and length of stay. (For more details on our process for evaluating relative costliness, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (73 FR 48543).) We believe in the rare event that there would be a few LTCH cases grouped to one of the no-volume proposed MS–LTC–DRGs in FY 2021, the proposed relative weights assigned based on the cross-walked proposed MS–LTC–DRGs would result in an appropriate LTCH PPS payment because the crosswalks, which are based on clinical similarity and relative costliness, would be expected to generally require equivalent relative resource use.

Then we assigned the proposed relative weight of the cross-walked proposed MS–LTC–DRG as the proposed relative weight for the no-volume proposed MS–LTC–DRG such that both of these proposed MS–LTC–DRGs (that is, the no-volume proposed MS–LTC–DRG and the cross-walked proposed MS–LTC–DRG) have the same proposed relative weight (and average length of stay) for FY 2021. We note that, if the cross-walked proposed MS–LTC–DRG had 25 applicable LTCH cases or more, its proposed relative weight (calculated using the methodology as previously described in Steps 1 through 4) is assigned to the no-volume proposed MS–LTC–DRG as well. Similarly, if the proposed MS–LTC–DRG to which the no-volume proposed MS–LTC–DRG was cross-walked had 24 or less cases and, therefore, was designated to 1 of the proposed low-volume quintiles for purposes of determining the proposed relative weights, we assigned the proposed relative weight of the applicable proposed low-volume quintile to the no-volume proposed MS–LTC–DRG such that both of these proposed MS–LTC–DRGs (that is, the no-volume proposed MS–LTC–DRG and the cross-walked proposed MS–LTC–DRG) have the same proposed relative weight for FY 2021. (As we noted previously, in the infrequent case where nonmonotonicity involving a no-volume proposed MS–LTC–DRG resulted, additional adjustments as described in Step 6 are required in order to maintain monotonically increasing proposed relative weights.)

As discussed earlier, for this proposed rule, we are providing the list of the no-volume proposed MS–LTC–DRGs and the proposed MS–LTC–DRGs to which each was cross-walked (that is, the cross-walked proposed MS–LTC–DRGs) for FY 2021 in a supplemental data file for public use posted via the internet on the CMS website for this proposed rule at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* in order to streamline the information made available to the public that is used in the annual development of Table 11.

To illustrate this methodology for determining the proposed relative weights for the proposed FY 2021 MS–LTC–DRGs with no applicable LTCH cases, we are providing the following example, which refers to the no-volume proposed MS–LTC–DRGs crosswalk information for FY 2021 (which, as previously stated, we are providing in a supplemental data file posted via the internet on the CMS website for this proposed rule).

Example: There were no trimmed applicable LTCH cases in the FY 2019 MedPAR file that we are using for this proposed rule for proposed MS–LTC–DRG 061 (Acute Ischemic Stroke with Use of Thrombolytic Agent with MCC). We determined that proposed MS–LTC–DRG 070 (Nonspecific Cerebrovascular Disorders with MCC) is similar clinically and based on resource use to proposed MS–LTC–DRG 061. Therefore, we assigned the same proposed relative weight (and average length of stay) of proposed MS–LTC–DRG 70 of 0.6954 for FY 2021 to proposed MS–LTC–DRG 061 (we refer readers to Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the internet on the CMS website).

Again, we note that, as this system is dynamic, it is entirely possible that the number of proposed MS–LTC–DRGs with no volume will vary in the future. Consistent with our historical practice, we are proposing to use the most recent available claims data to identify the trimmed applicable LTCH cases from which we determine the relative weights in the final rule.

For FY 2021, consistent with our historical relative weight methodology, we are proposing to establish a proposed relative weight of 0.0000 for the following transplant proposed MS–LTC–DRGs: Heart Transplant or Implant of Heart Assist System with MCC (MS–LTC–DRG 001); Heart Transplant or Implant of Heart Assist System without MCC (MS–LTC–DRG 002); Liver Transplant with MCC or Intestinal Transplant (MS–LTC–DRG 005); Liver Transplant without MCC (MS–LTC–DRG 006); Lung Transplant (MS–LTC–DRG 007); Simultaneous Pancreas/Kidney Transplant (MS–LTC–DRG 008); Simultaneous Pancreas/Kidney Transplant with Hemodialysis (proposed MS–LTC–DRG 019); Pancreas Transplant (MS–LTC–DRG 010); Kidney Transplant (MS–LTC–DRG 652); Kidney Transplant with Hemodialysis with MCC (proposed MS–LTC–DRG 650), and Kidney Transplant with Hemodialysis without MCC (proposed MS LTC DRG 651). This is because Medicare only covers these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified. At the present time, we include these 11 proposed transplant MS–LTC–DRGs in the GROUPER program for administrative purposes only. Because we use the same GROUPER program for LTCHs as is used under the IPPS,

removing these MS–LTC–DRGs would be administratively burdensome. (For additional information regarding our treatment of transplant MS–LTC–DRGs, we refer readers to the RY 2010 LTCH PPS final rule (74 FR 43964).) In addition, consistent with our historical policy, we are proposing to establish a relative weight of 0.0000 for the 2 ''error'' MS–LTC–DRGs (that is, MS–LTC–DRG 998 (Principal Diagnosis Invalid as Discharge Diagnosis) and MS–LTC–DRG 999 (Ungroupable)) because applicable LTCH cases grouped to these MS–LTC–DRGs cannot be properly assigned to an MS–LTC–DRG according to the grouping logic.

Additionally, we are proposing to establish a relative weight of 0.0000 for the following ''psychiatric or rehabilitation'' MS–LTC–DRGs: MS–LTC–DRG 876 (O.R. Procedure with Principal Diagnoses of Mental Illness); MS–LTC–DRG 880 (Acute Adjustment Reaction & Psychosocial Dysfunction); MS–LTC–DRG 881 (Depressive Neuroses); MS–LTC–DRG 882 (Neuroses Except Depressive); MS–LTC–DRG 883 (Disorders of Personality & Impulse Control); MS–LTC–DRG 884 (Organic Disturbances & Mental Retardation); MS–LTC–DRG 885 (Psychoses); MS–LTC–DRG 886 (Behavioral & Developmental Disorders); MS–LTC–DRG 887 (Other Mental Disorder Diagnoses); MS–LTC–DRG 894 (Alcohol/Drug Abuse or Dependence, Left Ama); MS–LTC–DRG 895 (Alcohol/Drug Abuse or Dependence, with Rehabilitation Therapy); MS–LTC–DRG 896 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy with MCC); MS–LTC–DRG 897 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy without MCC); MS–LTC–DRG 945 (Rehabilitation with CC/MCC); and MS–LTC–DRG 946 (Rehabilitation without CC/MCC). We are proposing a relative weight 0.0000 for these 15 ''psychiatric or rehabilitation'' MS LTC DRGs because the blended payment rate and temporary exceptions to the site neutral payment rate will not be applicable for any LTCH discharges occurring in FY 2021, and as such payment under the LTCH PPS will be no longer be made in part based on the LTCH PPS standard Federal payment rate for any discharges assigned to those MS–DRGs.

Step 6—Adjust the proposed FY 2021 MS–LTC–DRG relative weights to account for nonmonotonically increasing relative weights.

The MS–DRGs contain base DRGs that have been subdivided into one, two, or three severity of illness levels. Where there are three severity levels, the most severe level has at least one secondary diagnosis code that is referred to as an MCC (that is, major complication or comorbidity). The next lower severity level contains cases with at least one secondary diagnosis code that is a CC (that is, complication or comorbidity). Those cases without an MCC or a CC are referred to as ''without CC/MCC.'' When data do not support the creation of three severity levels, the base MS–DRG is subdivided into either two levels or the base MS–DRG is not subdivided. The two-level subdivisions may consist of the MS–DRG with CC/MCC and the MS–DRG without CC/MCC. Alternatively, the other type of two-level subdivision may consist of the MS–DRG with MCC and the MS–DRG without MCC.

In those base MS–LTC–DRGs that are split into either two or three severity levels, cases classified into the ''without CC/MCC'' MS–LTC–DRG are expected to have a lower resource use (and lower costs) than the ''with CC/MCC'' MS–LTC–DRG (in the case of a two-level split) or both the ''with CC'' and the ''with MCC'' MS–LTC–DRGs (in the case of a three-level split). That is, theoretically, cases that are more severe typically require greater expenditure of medical care resources and would result in higher average charges. Therefore, in the three severity levels, relative weights should increase by severity, from lowest to highest. If the relative weights decrease as severity increases (that is, if within a base MS–LTC–DRG, an MS–LTC–DRG with CC has a higher relative weight than one with MCC, or the MS–LTC–DRG ''without CC/MCC'' has a higher relative weight than either of the others), they are nonmonotonic. We continue to believe that utilizing nonmonotonic relative weights to adjust Medicare payments would result in inappropriate payments because the payment for the cases in the higher severity level in a base MS–LTC–DRG (which are generally expected to have higher resource use and costs) would be lower than the payment for cases in a lower severity level within the same base MS–LTC–DRG (which are generally expected to have lower resource use and costs). Therefore, in determining the proposed FY 2021 MS–LTC–DRG relative weights, consistent with our historical methodology, we are proposing to continue to combine MS–LTC–DRG severity levels within a base MS–LTC–DRG for the purpose of computing a relative weight when necessary to ensure that monotonicity is maintained. For a comprehensive description of our existing methodology to adjust for nonmonotonicity, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43964 through 43966). Any adjustments for nonmonotonicity that were made in determining the proposed FY 2021 MS–LTC–DRG relative weights in this proposed rule by applying this methodology are denoted in Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the internet on the CMS website.

Step 7— Calculate the proposed FY 2021 MS–LTC–DRG reclassification and recalibration budget neutrality factor.

In accordance with the regulations at § 412.517(b) (in conjunction with § 412.503), the annual update to the MS–LTC–DRG classifications and relative weights is done in a budget neutral manner such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the MS–LTC–DRG classification and relative weight changes. (For a detailed discussion on the establishment of the budget neutrality requirement for the annual update of the MS–LTC–DRG classifications and relative weights, we refer readers to the RY 2008 LTCH PPS final rule (72 FR 26881 and 26882).)

The MS–LTC–DRG classifications and relative weights are updated annually based on the most recent available LTCH claims data to reflect changes in relative LTCH resource use (§ 412.517(a) in conjunction with § 412.503). To achieve the budget neutrality requirement at § 412.517(b), under our established methodology, for each annual update, the MS–LTC–DRG relative weights are uniformly adjusted to ensure that estimated aggregate payments under the LTCH PPS would not be affected (that is, decreased or increased). Consistent with that provision, we are proposing to update the MS–LTC–DRG classifications and relative weights for FY 2021 based on the most recent available LTCH data for applicable LTCH cases, and continue to apply a budget neutrality adjustment in determining the FY 2021 MS–LTC–DRG relative weights.

In this proposed rule, to ensure budget neutrality in the update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), we are proposing to continue to use our established two-step budget neutrality methodology.

To calculate the proposed normalization factor for FY 2021, we are proposing to group applicable LTCH cases using the proposed FY 2021 Version 38 GROUPER, and the recalibrated proposed FY 2021 MS–

LTC–DRG relative weights to calculate the average case-mix index (CMI); we grouped the same applicable LTCH cases using the FY 2020 GROUPER Version 37 and MS–LTC–DRG relative weights and calculated the average CMI; and computed the ratio by dividing the average CMI for FY 2020 by the average CMI for proposed FY 2021. That ratio is the proposed normalization factor. Because the calculation of the proposed normalization factor involves the proposed relative weights for the proposed MS–LTC–DRGs that contained applicable LTCH cases to calculate the average CMIs, any low-volume proposed MS–LTC–DRGs are included in the calculation (and the proposed MS–LTC–DRGs with no applicable LTCH cases are not included in the calculation).

To calculate the proposed budget neutrality adjustment factor, we simulated estimated total FY 2021 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the proposed FY 2021 normalized relative weights and proposed GROUPER Version 38; simulated estimated total FY 2021 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2020 MS–LTC–DRG relative weights and the FY 2020 GROUPER Version 37; and calculated the ratio of these estimated total payments by dividing the simulated estimated total LTCH PPS standard Federal payment rate payments using the FY 2020 MS–LTC–DRG relative weights and the GROUPER Version 37 by the simulated estimated total LTCH PPS standard Federal payment rate payments using the proposed FY 2021 MS–LTC–DRG relative weights and the proposed GROUPER Version 38. The resulting ratio is the proposed budget neutrality adjustment factor. The calculation of the proposed budget neutrality factor involves the proposed relative weights for the LTCH cases used in the payment simulation, which includes any cases grouped to low-volume proposed MS–LTC–DRGs or to proposed MS–LTC–DRGs with no applicable LTCH cases, and generally does not include payments for cases grouped to a proposed MS–LTC–DRG with no applicable LTCH cases. (Occasionally, a few LTCH cases (that is, those with a covered length of stay of 7 days or less), which are removed from the proposed relative weight calculation in step 2 that are grouped to a proposed MS–LTC–DRG with no applicable LTCH cases are included in the payment simulations used to calculate the proposed budget neutrality factor. However, the number and payment amount of such cases have a negligible impact on the proposed budget neutrality factor calculation).

In this proposed rule, to ensure budget neutrality in the update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), we are proposing to continue to use our established two-step budget neutrality methodology. Therefore, in this proposed rule, in the first step of our MS–LTC–DRG budget neutrality methodology, for FY 2021, we are proposing to calculate and apply a proposed normalization factor to the recalibrated proposed relative weights (the result of Steps 1 through 6 discussed previously) to ensure that estimated payments are not affected by changes in the composition of case types or the proposed changes to the classification system. That is, the proposed normalization adjustment is intended to ensure that the recalibration of the proposed MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average case-mix index.

To calculate the proposed normalization factor for FY 2021 (the first step of our budget neutrality methodology), we used the following three steps: (1.a.) Use the most recent available applicable LTCH cases from the most recent available data (that is, LTCH discharges from the FY 2019 MedPAR file) and grouped them using the proposed FY 2021 GROUPER (that is, proposed Version 38 for FY 2021) and the recalibrated proposed FY 2021 MS–LTC–DRG relative weights (determined in Steps 1 through 6 discussed previously) to calculate the average case-mix index; (1.b.) group the same applicable LTCH cases (as are used in Step 1.a.) using the FY 2020 GROUPER (Version 37) and FY 2020 MS–LTC–DRG relative weights and calculated the average case-mix index; and (1.c.) compute the ratio of these average case-mix indexes by dividing the average CMI for FY 2021 (determined in Step 1.a.) by the average case-mix index for FY 2020 (determined in Step 1.b.). As a result, in determining the proposed MS–LTC–DRG relative weights for FY 2021, each recalibrated proposed MS–LTC–DRG relative weight is multiplied by the proposed normalization factor of 1.25878 (determined in Step 1.c.) in the first step of the proposed budget neutrality methodology, which produced ''normalized relative weights.''

In the second step of our MS–LTC–DRG budget neutrality methodology, we calculated a second budget neutrality factor consisting of the ratio of estimated aggregate FY 2021 LTCH PPS standard Federal payment rate payments for applicable LTCH cases (the sum of all calculations under Step 1.a. mentioned previously) after reclassification and recalibration to estimated aggregate payments for FY 2021 LTCH PPS standard Federal payment rate payments for applicable LTCH cases before reclassification and recalibration (that is, the sum of all calculations under Step 1.b. mentioned previously).

That is, for this proposed rule, for FY 2021, under the second step of the budget neutrality methodology, we are proposing to determine the proposed budget neutrality adjustment factor using the following three steps: (2.a.) Simulate estimated total FY 2021 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the proposed normalized relative weights for FY 2021 and proposed GROUPER Version 38 (as described previously); (2.b.) simulate estimated total FY 2021 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2020 GROUPER (Version 37) and the FY 2020 MS–LTC–DRG relative weights in Table 11 of the FY 2020 IPPS/LTCH PPS final rule available on the internet, as described in section VI. of the Addendum of that final rule; and (2.c.) calculate the ratio of these estimated total payments by dividing the value determined in Step 2.b. by the value determined in Step 2.a. In determining the proposed FY 2021 MS–LTC–DRG relative weights, each normalized proposed relative weight is then multiplied by a budget neutrality factor of 0.9993445 (the value determined in Step 2.c.) in the second step of the budget neutrality methodology to achieve the budget neutrality requirement at § 412.517(b).

Accordingly, in determining the proposed FY 2021 MS–LTC–DRG relative weights in this proposed rule, consistent with our existing methodology, we are proposing to apply a normalization factor of 1.25878 and a budget neutrality factor of 0.9993445. Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the internet on the CMS website, lists the proposed MS–LTC–DRGs and their respective proposed relative weights, geometric mean length of stay, and five-sixths of the geometric mean length of stay (used to identify SSO cases under § 412.529(a)) for FY 2021.

C. Proposed Changes to the LTCH PPS Payment Rates and Other Changes to the LTCH PPS for FY 2021

1. Overview of Development of the LTCH PPS Standard Federal Payment Rates

The basic methodology for determining LTCH PPS standard Federal payment rates is currently set forth at 42 CFR 412.515 through 412.533 and 412.535. In this section, we discuss the factors that we are proposing to use to update the LTCH PPS standard Federal payment rate for FY 2021, that is, effective for LTCH discharges occurring on or after October 1, 2020 through September 30, 2021. Under the dual rate LTCH PPS payment structure required by statute, beginning with discharges in cost reporting periods beginning in FY 2016, only LTCH discharges that meet the criteria for exclusion from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate specified at § 412.523. (For additional details on our finalized policies related to the dual rate LTCH PPS payment structure required by statute, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623).)

Prior to the implementation of the dual payment rate system in FY 2016, all LTCH discharges were paid similarly to those now exempt from the site neutral payment rate. That legacy payment rate was called the standard Federal rate. For details on the development of the initial standard Federal rate for FY 2003, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56037). For subsequent updates to the standard Federal rate (FYs 2003 through 2015)/LTCH PPS standard Federal payment rate (FY 2016 through present) as implemented under § 412.523(c)(3), we refer readers to the FY 2020IPPS/LTCH PPS final rule (84 FR 42445 through 42446).

In this FY 2021 IPPS/LTCH PPS proposed rule, we present our proposals related to the annual update to the LTCH PPS standard Federal payment rate for FY 2021.

The proposed update to the LTCH PPS standard Federal payment rate for FY 2021 is presented in section V.A. of the Addendum to this proposed rule. The components of the proposed annual update to the LTCH PPS standard Federal payment rate for FY 2021 are discussed in this section, including the statutory reduction to the annual update for LTCHs that fail to submit quality reporting data for FY 2021 as required by the statute (as discussed in section VII.C.2.c. of the preamble of this proposed rule). We are also proposing to make an adjustment to the LTCH PPS standard Federal payment rate to account for the estimated effect of the changes to the area wage level for FY 2021 on estimated aggregate LTCH PPS payments, in accordance with § 412.523(d)(4) (as discussed in section V.B. of the Addendum to this proposed rule).

In addition, as discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41532 through 41537), we eliminated the 25-percent threshold policy in a budget neutral manner. The budget neutrality requirements are codified in the regulations at § 412.523(d)(6). Under these regulations, a temporary, one-time factor is applied to the standard Federal payment rate in FY 2019 and FY 2020, and a permanent, one-time factor in FY 2021. These factors as established in the correction to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41536) are—

- For FY 2019, a temporary, one-time factor of 0.990878;
- For FY 2020, a temporary, one-time factor of 0.990737; and
- For FY 2021 and subsequent years, a permanent, one-time factor of 0.991249.

Therefore, in determining the FY 2021 LTCH PPS standard Federal payment rate, we are proposing to—

- Remove the temporary, one-time factor of 0.990737 for the estimated cost of the elimination of the 25-percent threshold policy in FY 2020 by applying a factor of (1/0.990737);
- Apply a permanent, one-time factor of 0.991249 for the estimated cost of the elimination of the 25-percent threshold policy in FY 2021;

2. Proposed FY 2021 LTCH PPS Standard Federal Payment Rate Annual Market Basket Update

a. Overview

Historically, the Medicare program has used a market basket to account for input price increases in the services furnished by providers. The market basket used for the LTCH PPS includes both operating and capital related costs of LTCHs because the LTCH PPS uses a single payment rate for both operating and capital-related costs. We adopted the 2013-based LTCH market basket for use under the LTCH PPS beginning in FY 2017 (81 FR 57100 through 57102). As discussed in section VII.D. of the preamble of this proposed rule, we are proposing to rebase and revise the 2013-based LTCH market basket to reflect a 2017 base year. For additional details on the historical development of the market basket used under the LTCH PPS, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53476), and for a complete discussion of the LTCH market basket and a description of the methodologies used to determine the operating and capital-related portions of the 2013-based LTCH market basket, we refer readers to section VII.D. of the preamble of the FY 2017 IPPS/LTCH PPS proposed and final rules (81 FR 25153 through 25167 and 81 FR 57086 through 57099, respectively).

Section 3401(c) of the Affordable Care Act provides for certain adjustments to any annual update to the LTCH PPS standard Federal payment rate and refers to the timeframes associated with such adjustments as a ''rate year.'' We note that, because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010, to conform with the standard definition of the Federal fiscal year (October 1 through September 30) used by other PPSs, such as the IPPS (75 FR 50396 through 50397). Although the language of sections 3004(a), 3401(c), 10319, and 1105(b) of the Affordable Care Act refers to years 2010 and thereafter under the LTCH PPS as ''rate year,'' consistent with our change in the terminology used under the LTCH PPS from ''rate year'' to ''fiscal year,'' for purposes of clarity, when discussing the annual update for the LTCH PPS standard Federal payment rate, including the provisions of the Affordable Care Act, we use ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.

b. Proposed Annual Update to the LTCH PPS Standard Federal Payment Rate for FY 2021

CMS has used an estimated market basket increase to update the LTCH PPS. As previously noted, for FY 2021 we are proposing to rebase and revise the 2013-based LTCH market basket to reflect a 2017 base year. The proposed 2017-based LTCH market basket is primarily based on the Medicare cost report data submitted by LTCHs and, therefore, specifically reflects the cost structures of only LTCHs. We are proposing to use data from cost reports beginning in FY 2017 because these data are the latest available complete data at the time of rulemaking for purposes of calculating cost weights for the market basket. We believe that the proposed 2017-based LTCH market basket appropriately reflects the cost structure of LTCHs, as discussed in greater detail in section VII.D. of the preamble of this proposed rule. In this proposed rule, we are proposing to use the proposed 2017-

based LTCH market basket to update the LTCH PPS standard Federal payment rate for FY 2021.

Section 1886(m)(3)(A) of the Act provides that, beginning in FY 2010, any annual update to the LTCH PPS standard Federal payment rate is reduced by the adjustments specified in clauses (i) and (ii) of subparagraph (A). Clause (i) of section 1886(m)(3)(A) of the Act provides for a reduction, for FY 2012 and each subsequent rate year, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (that is, ''the multifactor productivity (MFP) adjustment''). Clause (ii) of section 1886(m)(3)(A) of the Act provided for a reduction, for each of FYs 2010 through 2019, by the ''other adjustment'' described in section 1886(m)(4)(F) of the Act; therefore, it is not applicable for FY 2021.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year.

c. Proposed Adjustment to the LTCH PPS Standard Federal Payment Rate Under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In accordance with section 1886(m)(5) of the Act, the Secretary established the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). The reduction in the annual update to the LTCH PPS standard Federal payment rate for failure to report quality data under the LTCH QRP for FY 2014 and subsequent fiscal years is codified under 42 CFR 412.523(c)(4). The LTCH QRP, as required for FY 2014 and subsequent fiscal years by section 1886(m)(5)(A)(i) of the Act, applies a 2.0 percentage point reduction to any update under § 412.523(c)(3) for an LTCH that does not submit quality reporting data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a year (that is, in the form and manner and at the time specified by the Secretary under the LTCH QRP) (§ 412.523(c)(4)(i)). Section 1886(m)(5)(A)(ii) of the Act provides that the application of the 2.0 percentage points reduction may result in an annual update that is less than 0.0 for a year, and may result in LTCH PPS payment rates for a year being less than such LTCH PPS payment rates for the preceding year. Furthermore, section 1886(m)(5)(B) of the Act specifies that the 2.0 percentage points reduction is applied in a noncumulative manner, such that any reduction made under section 1886(m)(5)(A) of the Act shall apply only with respect to the year involved, and shall not be taken into account in computing the LTCH PPS payment amount for a subsequent year. These requirements are codified in the regulations at § 412.523(c)(4). (For additional information on the history of the LTCH QRP, including the statutory authority and the selected measures, we refer readers to section VIII.C. of the preamble of this proposed rule.)

d. Proposed Annual Market Basket Update Under the LTCH PPS for FY 2021

Consistent with our historical practice and our proposal, we estimate the market basket increase and the MFP adjustment based on IGI's forecast using the most recent available data. Based on IGI's fourth quarter 2019 forecast, the FY 2021 full market basket estimate for the LTCH PPS using the proposed 2017-based LTCH market basket is 2.9 percent. The current estimate of the MFP adjustment for FY 2021 based on IGI's fourth quarter 2019 forecast is 0.4 percent.

For FY 2021, section 1886(m)(3)(A)(i) of the Act requires that any annual update to the LTCH PPS standard Federal payment rate be reduced by the productivity adjustment (''the MFP adjustment'') described in section 1886(b)(3)(B)(xi)(II) of the Act. Consistent with the statute, we are proposing to reduce the full estimated FY 2021 market basket increase by the FY 2021 MFP adjustment. To determine the proposed market basket increase for LTCHs for FY 2021, as reduced by the proposed MFP adjustment, consistent with our established methodology, we are subtracting the proposed FY 2021 MFP adjustment from the estimated FY 2021 market basket increase. (We note that sections 1886(m)(3)(A)(ii) and 1886(m)(4)(F) of the Act required an additional reduction each year only for FYs 2010 through 2019.) (For additional details on our established methodology for adjusting the market basket increase by the MFP adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771).)

For FY 2021, section 1886(m)(5) of the Act requires that, for LTCHs that do not submit quality reporting data as required under the LTCH QRP, any annual update to an LTCH PPS standard Federal payment rate, after application of the adjustments required by section 1886(m)(3) of the Act, shall be further reduced by 2.0 percentage points. Therefore, for LTCHs that fail to submit quality reporting data under the LTCH QRP, the proposed 2.9 percent update to the LTCH PPS standard Federal payment rate for FY 2021 would be reduced by the 0.4 percentage point MFP adjustment as required under section 1886(m)(3)(A)(i) of the Act and the additional 2.0 percentage points reduction required by section 1886(m)(5) of the Act.

In this FY 2021 IPPS/LTCH PPS proposed rule, in accordance with the statute, we are proposing to reduce the proposed FY 2021 full market basket estimate of 2.9 percent (based on IGI's fourth quarter 2019 forecast of the proposed 2017-based LTCH market basket) by the proposed FY 2021 MFP adjustment of 0.4 percentage point (based on IGI's fourth quarter 2019 forecast). Therefore, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we are proposing to establish an annual market basket update to the LTCH PPS standard Federal payment rate for FY 2021 of 2.5 percent (that is, the most recent estimate of the LTCH PPS market basket increase of 2.9 percent less the MFP adjustment of 0.4 percentage point). While we have historically implemented the payment updates to the LTCH PPS in individual amendments to the regulations, given existing statutory provisions affecting the LTCH update are constant going forward, we are proposing to revise § 412.523(c)(3) by adding a new paragraph (xvii), which would specify that the LTCH PPS standard Federal payment rate for FY 2021 and subsequent fiscal years is the LTCH PPS standard Federal payment rate for the previous LTCH PPS payment year updated by the market basket (as determined by CMS), less a multifactor productivity adjustment (as determined by CMS), and further adjusted, as appropriate, as described in § 412.523(d) (including the application of the adjustment factor for the cost of the elimination of the 25-percent threshold policy under § 412.523(d)(6) as previously discussed) rather than codifying specific numerical updates annually as was our historical practice. For LTCHs that fail to submit quality reporting data under the LTCH QRP, under § 412.523(c)(3)(xvi) in conjunction with § 412.523(c)(4), we are proposing to further reduce the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points, in accordance with section 1886(m)(5) of the Act. Accordingly, we are proposing to establish an annual update to the LTCH PPS standard Federal payment rate of 0.5 percent (that is, 2.5 percent minus 2.0 percentage points) for FY 2021 for LTCHs that fail to submit quality reporting data as required under the LTCH QRP.

Consistent with our historical practice, we are proposing to use a more recent estimate of the market basket and the MFP adjustment, if appropriate, in the final rule to establish an annual update to the LTCH PPS standard Federal payment rate for FY 2021 under proposed § 412.523(c)(3)(xvii). (We note that, consistent with historical practice, we are also proposing to adjust the FY 2021 LTCH PPS standard Federal payment rate by an area wage level budget neutrality factor in accordance with § 412.523(d)(4) (as discussed in section V.B.5. of the Addendum to this proposed rule).)

D. Proposed Rebasing of the LTCH Market Basket

1. Background

The input price index (that is, the market basket) that was used to develop the LTCH PPS for FY 2003 was the ''excluded hospital with capital'' market basket. That market basket was based on 1997 Medicare cost report data and included data for Medicare-participating IRFs, IPFs, LTCHs, cancer hospitals, and children's hospitals. Although the term ''market basket'' technically describes the mix of goods and services used in providing hospital care, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies combined) derived from that mix. Accordingly, the term ''market basket,'' as used in this section, refers to an input price index.

Beginning with rate year (RY) 2007, LTCH PPS payments were updated using a 2002-based market basket reflecting the operating and capital cost structures for IRFs, IPFs, and LTCHs (hereafter referred to as the rehabilitation, psychiatric, and long-term care (RPL) market basket). We excluded cancer and children's hospitals from the RPL market basket because their payments are based entirely on reasonable costs subject to rate-of-increase limits established under the authority of section 1886(b) of the Act, which are implemented in regulations at 42 CFR 413.40. Those types of hospitals are not paid under a PPS. Also, the 2002 cost structures for cancer and children's hospitals are noticeably different from the cost structures for freestanding IRFs, freestanding IPFs, and LTCHs. A complete discussion of the 2002-based RPL market basket can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817).

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51756), we finalized the rebasing and revising of the 2002-based RPL market basket by creating and implementing a 2008-based RPL market basket. We also discussed the creation of a stand-alone LTCH market basket and received several public comments, all of which supported deriving a standalone LTCH market basket (76 FR 51756 through 51757). In the FY 2013 IPPS/LTCH PPS final rule, we finalized the adoption of a stand-alone 2009-based LTCH-specific market basket that reflects the cost structures of LTCHs only (77 FR 53467 through 53479). In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57085 through 57099), we finalized the rebasing and revising of the 2009-based LTCH market basket to reflect a 2013 base year (the 2013-based LTCH market basket).

For this FY 2021 IPPS/LTCH PPS proposed rule, we propose to rebase and revise the 2013-based LTCH market basket to reflect a 2017 base year. The proposed 2017-based LTCH market basket is primarily based on Medicare cost report data for LTCHs for 2017, which are for cost reporting periods beginning on and after October 1, 2016, and prior to October 1, 2017. We propose to use data from cost reports beginning in FY 2017 because these data are the latest available complete data for purposes of calculating cost weights for the market basket at the time of rulemaking.

In the following discussion, we provide an overview of the proposed LTCH market basket, describe the proposed methodologies for developing the operating and capital portions of the 2017-based LTCH market basket, and provide information on the proposed price proxies. Then, we present the FY 2021 market basket update and labor-related share based on the proposed 2017-based LTCH market basket.

2. Overview of the Proposed 2017-Based LTCH Market Basket

Similar to the 2013-based LTCH market basket, the proposed 2017-based LTCH 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 (that is, intensity) of goods and services purchased over time are not measured. The index itself is constructed using three steps. First, a base period is selected (in this proposed rule, we propose to use 2017 as the base period) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called ''cost weights'' or ''expenditure weights.'' Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a ''price proxy.'' In almost 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. As previously noted, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to furnish hospital services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, a hospital hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the hospital, but would not be factored into the price change measured by a fixed-weight hospital market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect a recent mix of goods and services that hospitals purchase (hospital inputs) to furnish inpatient care.

3. Development of the Proposed 2017-Based LTCH Market Basket Cost Categories and Weights

We are inviting public comments on our proposed methodology, discussed in this section of this rule, for deriving the proposed 2017-based LTCH market basket.

a. Use of Medicare Cost Report Data

We are proposing a 2017-based LTCH market basket that consists of seven major cost categories and a residual derived from the 2017 Medicare cost reports (CMS Form 2552–10, OMB Control Number 0938–0050) for LTCHs. The seven cost categories are Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, Professional

Liability Insurance (PLI), Home Office/Related Organization Contract Labor, and Capital. The residual category reflects all remaining costs not captured in the seven cost categories. The 2013-based LTCH market basket did not use the Medicare cost reports to calculate the Home Office/Related Organization Contract Labor cost weight.

Medicare cost report data include costs for all patients, including Medicare, Medicaid, and private payer. Because our goal is to measure cost shares for facilities that serve Medicare beneficiaries, and are reflective of case mix and practice patterns associated with providing services to Medicare beneficiaries in LTCHs, we propose to limit our selection of Medicare cost reports to those from LTCHs that have a Medicare average length of stay (LOS) that is within a comparable range of their total facility average LOS. We define the Medicare average LOS based on data reported on the Medicare cost report (CMS Form 2552–10, OMB Control Number 0938–0050) Worksheet S–3, Part I, line 14. We believe that applying the LOS edit results in a more accurate reflection of the structure of costs for Medicare covered days as our proposed edit excludes those LTCHs that had an average total facility LOS that was much different than the average Medicare LOS. For the 2013-based LTCH market basket, we used the cost reports submitted by LTCHs with Medicare average LOS within 25 percent (that is, 25 percent higher or lower) of the total facility average LOS for the hospital. Based on our analysis of the 2017 Medicare cost reports, for the proposed 2017-based LTCH market basket, we propose to again use the cost reports submitted by LTCHs with Medicare average LOS within 25 percent (that is, 25 percent higher or lower) of the total facility average LOS for the hospital. The universe of LTCHs had an average Medicare LOS of 26 days, an average total facility LOS of 31 days, and aggregate Medicare utilization (as measured by Medicare inpatient LTCH days as a percentage of total facility inpatient LTCH days) of 49 percent in 2017. Applying the proposed trim excludes 9 percent of LTCH providers and results in a subset of LTCH Medicare cost reports with an average Medicare LOS of 25 days, average facility LOS of 27 days, and aggregate Medicare utilization (based on days) of 58 percent. The 9 percent of providers that are excluded from the proposed 2017-based LTCH market basket had an average Medicare LOS of 27 days, average facility LOS of 70 days, and aggregate Medicare utilization of 15 percent.

We are proposing to use the cost reports for LTCHs that meet this requirement to calculate the costs for the seven major cost categories (Wages and Salaries, Employee Benefits, Contract Labor, Professional Liability Insurance, Pharmaceuticals, Home Office/Related Organization Contract Labor, and Capital) for the market basket. For comparison, the 2013-based LTCH market basket utilized the Bureau of Economic Analysis Benchmark Input-Output data rather than Medicare cost report data to derive the Home Office/Related Organization Contract Labor cost weight. A more detailed discussion of this methodological change is provided in section VII.D.3.a.(6). of the preamble of this proposed rule.

(1) Wages and Salaries Costs

We propose to derive Wages and Salaries costs as the sum of routine inpatient salaries, ancillary salaries, and a proportion of overhead (or general service cost center) salaries as reported on Worksheet A, column 1. Because overhead salary costs are attributable to the entire LTCH, we propose to only include the proportion attributable to the Medicare allowable cost centers. For the 2017-based LTCH market basket, we propose that routine and ancillary Wages and Salaries costs would be equal to salary costs as reported on Worksheet A, column 1, lines 30 through 35, 50 through 76 (excluding 52, 61, and 75), 90 through 91, and 93. Then, we are proposing to estimate the proportion of overhead salaries that are attributed to Medicare allowable costs centers by multiplying the ratio of these routine and ancillary Wages and Salaries to total salaries (Worksheet A, column 1, line 200) times total overhead salaries (Worksheet A, column 1, lines 4 through 18). A similar methodology was used to derive Wages and Salaries costs in the 2013-based LTCH market basket.

(2) Employee Benefits Costs

Similar to the 2013-based LTCH market basket, we propose to calculate Employee Benefits costs using Worksheet S–3, part II data. Specifically, we propose to use data from Worksheet S–3, part II, column 4, lines 17, 18, 20, and 22, to derive Employee Benefits costs. The completion of Worksheet S–3, part II is only required for IPPS hospitals. For 2017, we found that approximately 20 percent of LTCHs voluntarily reported these data, which has fallen from the roughly 35 percent that reported these data for 2013. Our analysis of the Worksheet S–3, part II data submitted by these LTCHs indicates that we continue to have a large enough sample to enable us to produce a reasonable Employee Benefits cost weight. Specifically, we found that when we recalculated the cost weight after weighting to reflect the characteristics of the universe of LTCHs (type of control (nonprofit, for-profit, and government) and by region), the recalculation did not have a material effect on the resulting cost weight. Therefore, we propose to use Worksheet S–3, part II data (as was done for the 2013-based LTCH market basket) to calculate the Employee Benefits cost weight in the proposed 2017-based LTCH market basket.

We note that, effective with the implementation of CMS Form 2552–10, OMB Control Number 0938–0050, we began collecting Employee Benefits and Contract Labor data on Worksheet S–3, part V, which is applicable to LTCHs. However, approximately 17 percent of LTCHs reported data on Worksheet S–3, part V for 2017, with most of these providers also reporting data on Worksheet S–3, part II. Because a greater percentage of LTCHs continue to report data on Worksheet S–3, part II than Worksheet S–3, part V for 2017, we are not proposing to use the Employee Benefits and Contract Labor data reported on Worksheet S–3, part V to calculate the Employee Benefits cost weight in the proposed 2017-based LTCH market basket. We continue to encourage all providers to report these data on Worksheet S–3, Part V.

(3) Contract Labor Costs

Contract Labor costs are primarily associated with direct patient care services. Contract Labor costs for services such as accounting, billing, and legal are estimated using other government data sources as described in this section of this proposed rule. Approximately 44 percent of LTCHs voluntarily reported Contract Labor costs on Worksheet S–3, part II, which was similar to the percentage obtained from 2013 Medicare cost reports. Only about 18 percent of LTCHs reported Contract Labor costs data on Worksheet S–3, part V.

As was done for the 2013-based LTCH market basket, we propose to derive the Contract Labor costs for the proposed 2017-based LTCH market basket using voluntarily reported data from Worksheet S–3, part II. Our analysis of these data indicates that we have a large enough sample to enable us to produce a reasonable Contract Labor cost weight. Specifically, we found that when we recalculated the cost weight after weighting to reflect the characteristics of

the universe of LTCHs (type of control (nonprofit, for-profit, and government) and by region), the recalculation did not have a material effect on the resulting cost weight. Therefore, we propose to use data from Worksheet S–3, part II, column 4, lines 11 and 13 to calculate the Contract Labor cost weight in the proposed 2017-based LTCH market basket.

(4) Pharmaceuticals Costs

We propose to calculate Pharmaceuticals costs using nonsalary costs for the pharmacy cost center (line 15) and drugs charged to patients cost center (line 73). We propose to estimate these costs using total pharmaceutical costs reported on Worksheet B, part I, column 0, lines 15 and 73 and then removing a portion of these costs attributable to salaries. We are proposing to estimate the proportion of costs for removal as Worksheet A, column 1, lines 15 and 73 divided by the sum of Worksheet A, columns 1 and 2, lines 15 and 73. A similar methodology was used for the 2013-based LTCH market basket.

(5) Professional Liability Insurance Costs

We propose that Professional Liability Insurance (PLI) costs (often referred to as malpractice costs) be equal to premiums, paid losses and self-insurance costs reported on Worksheet S–2, part I, columns 1 through 3, line 118. A similar methodology was used for the 2013-based LTCH market basket.

(6) Home Office/Related Organization Contract Labor Costs

For the 2017-based LTCH market basket, we propose to determine the Home Office/Related Organization Contract Labor costs using Medicare cost report data. Specifically, we propose to calculate the Home Office/Related Organization Contract Labor costs using data reported on Worksheet S–3, part II, column 4, lines 14, 1401, 1402, 2550, and 2551 for those LTCH providers reporting total salaries on Worksheet S–3, part II, line 1.

The 2013-based LTCH market basket used the 2007 Benchmark Input-Output (I–O) expense data published by the Bureau of Economic Analysis (BEA) to derive these costs (81 FR 57089). A more detailed explanation of the general methodology using the BEA I–O data is provided in section VII.D.3.c. of the preamble of this proposed rule. We calculated the Home Office/Related Organization Contract Labor cost weight using expense data for North American Industry Classification System (NAICS) code 55, Management of Companies and Enterprises (81 FR 57098). We believe the proposed methodology for the 2017-based LTCH market basket is a technical improvement over the prior methodology because it represents more recent data that is representative compositionally and geographically of LTCHs.

(7) Capital Costs

We propose that Capital costs be equal to Medicare allowable capital costs as reported on Worksheet B, part II, column 26, lines 30 through 35, 50 through 76 (excluding 52, 61, and 75), 90 through 91 and 93. A similar methodology was used for the 2013-based LTCH market basket.

b. Final Major Cost Category Computation

After we derive costs for the major cost categories for each provider using the Medicare cost report data as previously described, we propose to trim the data for outliers. For each of the seven major cost categories, we first are proposing to divide the calculated costs for the category by total Medicare allowable costs calculated for the provider to obtain cost weights for the universe of LTCH providers. For the 2017-based LTCH market basket (similar to the 2013-based LTCH market basket), we propose that total Medicare allowable costs would be equal to the total costs as reported on Worksheet B, part I, column 26, lines 30 through 35, 50 through 76 (excluding 52, 61 and 75), 90 through 91, and 93.

For the Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, Professional Liability Insurance, and Capital cost weights, after excluding cost weights that are less than or equal to zero, we propose to then remove those providers whose derived cost weights fall in the top and bottom 5 percent of provider specific derived cost weights to ensure the exclusion of outliers. After the outliers have been excluded, we sum the costs for each category across all remaining providers. We are proposing to divide this by the sum of total Medicare allowable costs across all remaining providers to obtain a cost weight for the 2017-based LTCH market basket for the given category. This trimming process is done for each cost weight separately.

For the Home Office/Related Organization Contract Labor cost weight, we propose to apply a 1-percent top only trimming methodology. This allows all providers' Medicare allowable costs to be included, even if their Home Office/Related Organization Contract Labor costs were zero. We believe, as the Medicare cost report data (Worksheet S–2, part I, line 140) indicate, that not all LTCHs have a home office. LTCHs 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, LTCHs 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. We believe this 1-percent top-only trimming methodology is appropriate as it addresses outliers while 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. If we applied both the top and bottom 5 percent trimming methodology, we would exclude providers who have zero Home Office/Related Organization Contract Labor costs.

Finally, we propose to calculate the residual ''All Other'' cost weight that reflects all remaining costs that are not captured in the seven cost categories listed. We refer readers to Table E1 for the resulting proposed cost weights for these major cost categories.

TABLE E1—MAJOR COST CATEGORIES AS DERIVED FROM MEDICARE COST REPORTS

Major Cost Categories	Proposed 2017-Based LTCH Market Basket (Percent)	2013-Based LTCH Market Basket (Percent)
Wages and Salaries	42.6	41.5
Employee Benefits	6.2	6.5
Contract Labor	4.4	5.9
Professional Liability Insurance (Malpractice)	0.5	0.9
Pharmaceuticals	6.2	7.6
Home Office/Related Organization Contract Labor	1.9	N/A
Capital	9.9	9.7
All Other	28.3	27.8

The Wages and Salaries cost weight calculated from the Medicare cost reports for the proposed 2017-based LTCH market basket is approximately 1 percentage point higher than the Wages and Salaries cost weight for the 2013-based LTCH market basket, while the Contract Labor cost weight is 1.5 percentage point lower. The proposed 2017-based Pharmaceuticals cost weight also is roughly 1.5 percentage point lower than the cost weight for the 2013-based LTCH market basket.

As we did for the 2013-based LTCH market basket, we propose to allocate the Contract Labor cost weight 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. This rounded percentage is 87 percent. Therefore, we propose to allocate 87 percent of the Contract Labor cost weight to the Wages and Salaries cost weight and 13 percent to the Employee Benefits cost weight. We refer readers to Table E2 that shows the proposed Wages and Salaries and Employee Benefits cost weights after Contract Labor cost weight allocation for both the proposed 2017-based LTCH market basket and the 2013-based LTCH market basket.

TABLE E2- WAGES AND SALARIES AND EMPLOYEE BENEFITS COST WEIGHTS AFTER CONTRACT LABOR ALLOCATION

Major Cost Categories	Proposed 2017-Based LTCH Market Basket	2013-Based LTCH Market Basket
Wages and Salaries	46.4	46.6
Employee Benefits	6.8	7.3
Compensation	53.2	53.9

After the allocation of the Contract Labor cost weight, the proposed 2017-based Wages and Salaries cost weight is 0.2 percentage point lower and the Employee Benefits cost weight is 0.5 percentage point lower, relative to the respective cost weights for the 2013-based LTCH market basket. As a result, in the proposed 2017-based LTCH market basket, the compensation cost weight is 0.7 percentage point lower than the Compensation cost weight for the 2013-based LTCH market basket.

c. Derivation of the Detailed Operating Cost Weights

To further divide the residual ''All Other'' cost weight estimated from the 2017 Medicare cost report data into more detailed cost categories, we propose to use the 2012 Benchmark I–O ''Use Tables/Before Redefinitions/Purchaser Value'' for NAICS 622000, Hospitals, published by the Bureau of Economic Analysis (BEA). These data are publicly available at the following website: *https://www.bea.gov/industry/input-output-accounts-data*. For the 2013-based LTCH market basket, we used the 2007 Benchmark I–O data, the most recent data available at the time (81 FR 57089).

The BEA Benchmark I–O data are scheduled for publication every 5 years with the most recent data available for 2012. 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.[471] BEA also produces Annual I–O estimates. However, while based on a similar methodology, these estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data becomes available. Instead of using the less detailed Annual I–O data, we propose to

[471] *http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.*

inflate the 2012 Benchmark I–O data forward to 2017 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. We repeated this practice for each year. Then, we calculated the cost shares that each cost category represents of the 2012 data inflated to 2017. These resulting 2017 cost shares were applied to the residual ''All Other'' cost weight to obtain the detailed cost weights for the proposed 2017-based LTCH market basket. For example, the cost for Food: Direct Purchases represents 4.9 percent of the sum of the residual ''All Other'' 2012 Benchmark I–O Hospital Expenditures inflated to 2017. Therefore, the Food: Direct Purchases cost weight represents 4.9 percent of the proposed 2017-based LTCH market basket's residual ''All Other'' cost category (28.3 percent), yielding a ''final'' Food: Direct Purchases proposed cost weight of 1.4 percent in the proposed 2017-based LTCH market basket (0.049 × 28.3 percent = 1.4 percent).

Using this methodology, we propose to derive 17 detailed LTCH market basket cost category weights from the proposed 2017-based LTCH market basket residual ''All Other'' cost weight (28.3 percent). These categories are: (1) Electricity; (2) Fuel, Oil, and Gasoline; (3) Food: Direct Purchases; (4) Food: Contract Services; (5) Chemicals; (6) Medical Instruments; (7) Rubber and Plastics; (8) Paper and Printing Products; (9) Miscellaneous Products; (10) Professional Fees: Labor-Related; (11) Administrative and Facilities Support Services; (12) Installation, Maintenance, and Repair Services; (13) All Other Labor-Related Services; (14) Professional Fees: Nonlabor-Related; (15) Financial Services; (16) Telephone Services; and (17) All Other Nonlabor-Related Services. We note that for the 2013-based LTCH market basket, we had a Water and Sewerage cost weight. For the proposed 2017-based LTCH market basket, we propose to include Water and Sewerage costs in the Electricity cost weight due to the small amount of costs in this category.

For the 2013-based LTCH market basket, we used the I–O data for NAICS 55 Management of Companies to derive the Home Office/Related Organization Contract Labor cost weight, which were classified in the Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost weights. As previously discussed, we propose to use the Medicare cost report data to derive the Home Office/Related Organization Contract Labor cost weight, which we would further classify into the Professional Fees: Labor-related or Professional Fees: Nonlabor-related categories which we discuss in section VII.D.6. of the preamble of this proposed rule.

d. Derivation of the Detailed Capital Cost Weights

As described in section VII.D.3.b. of the preamble of this proposed rule, we are proposing a Capital-related cost weight of 9.9 percent as calculated from the 2017 Medicare cost reports for LTCHs after applying the proposed trims as previously described. We propose to then separate this total Capital-related cost weight into more detailed cost categories. Using 2017 Medicare cost reports, we are able to group Capital-related costs into the following categories: Depreciation, Interest, Lease, and Other Capital-Related costs, as shown in Table E3. For each of these categories, we propose to determine what proportion of total Capital-related costs the category represents using the data reported by the LTCH on Worksheet A–7, which is the same methodology used for the 2013-based LTCH market basket.

We also are proposing to allocate lease costs across each of the remaining detailed Capital-related cost categories as was done in the 2013-based LTCH market basket. This would result in three primary Capital-related cost categories in the proposed 2017-based LTCH market basket: Depreciation, Interest, and Other Capital-Related costs. Lease costs are unique in that they are not broken out as a separate cost category in the proposed 2017-based LTCH market basket. Rather we propose to proportionally distribute these costs among the cost categories of Depreciation, Interest, and Other Capital-Related, reflecting the assumption that the underlying cost structure of leases is similar to that of Capital-related costs in general. As was done for the 2013-based LTCH market basket, we propose to assume that 10 percent of the lease costs as a proportion of total Capital-related costs (63.0 percent) represents overhead and to assign those costs to the Other Capital-Related cost category accordingly. Therefore, we are assuming that approximately 6.3 percent (63.0 percent × 0.1) of total Capital-related costs represent lease costs attributable to overhead, and we propose to add this 6.3 percentage points to the 6.7 percent Other Capital-Related cost category weight. We are also proposing to distribute the remaining lease costs (56.7 percent, or 63.0 percent less 6.3 percentage points) proportionally across the three cost categories (Depreciation, Interest, and Other Capital-Related) based on the proportion that these categories comprise of the sum of the Depreciation, Interest, and Other Capital-Related cost categories (excluding lease expenses). For example, the Other Capital-Related cost category represented 18.2 percent of all three cost categories (Depreciation, Interest, and Other Capital-Related) prior to any lease expenses being allocated. This 18.2 percent is applied to the 56.7 percent of remaining lease expenses so that another 10.3 percentage points of lease expenses as a percent of total Capital-related costs is allocated to the Other Capital-Related cost category. Therefore, the resulting proposed Other Capital-Related cost weight is 23.3 percent (6.7 percent + 6.3 percent + 10.3 percent). This is the same methodology used for the 2013-based LTCH market basket. The proposed allocation of these lease expenses are shown in Table E3.

Finally, we propose to further divide the Depreciation and Interest cost categories. We propose to separate Depreciation cost category into the following two categories: (1) Building and Fixed Equipment and (2) Movable Equipment. We also propose to separate the Interest cost category into the following two categories: (1) Government/Nonprofit; and (2) For profit.

To disaggregate the Depreciation cost weight, we needed to determine the percent of total depreciation costs for LTCHs (after the allocation of lease costs) that are attributable to Building and Fixed equipment, which we hereafter refer to as the ''fixed percentage.'' We propose to use depreciation and lease data from Worksheet A–7 of the 2017 Medicare cost reports, which is the same methodology used for the 2013-based LTCH market basket. Based on the 2017 LTCH Medicare cost report data, we have determined that depreciation costs for building and fixed equipment account for 44 percent of total depreciation costs, while depreciation costs for movable equipment account for 56 percent of total depreciation costs. As previously mentioned, we propose to allocate lease expenses among the Depreciation, Interest, and Other Capital-Related cost categories. We determined that leasing building and fixed equipment expenses account for 88 percent of total leasing expenses, while leasing movable equipment expenses account for 12 percent of total leasing expenses. We propose to sum the depreciation and leasing expenses for building and fixed equipment, as

well as sum the depreciation and leasing expenses for movable equipment. This results in the proposed Building and Fixed Equipment Depreciation cost weight (after leasing costs are included) representing 76 percent of total depreciation costs and the Movable Equipment Depreciation cost weight (after leasing costs are included) representing 24 percent of total depreciation costs.

To disaggregate the Interest cost weight, we determine the percent of total interest costs for LTCHs that are attributable to government and nonprofit facilities, which we hereafter refer to as the ''nonprofit percentage,'' because price pressures associated with these types of interest costs tend to differ from those for for-profit facilities. We propose to use interest costs data from Worksheet A–7 of the 2017 Medicare cost reports for LTCHs, which is the same methodology used for the 2013-based LTCH market basket. The nonprofit percentage determined using this method is 21 percent.

Table E3 provides the proposed detailed capital cost shares obtained from the Medicare cost reports. Ultimately, if finalized, these detailed capital cost shares would be applied to the total Capital-related cost weight determined in section VII.D.3.b. of the preamble of this proposed rule to separate the total Capital-related cost weight of 9.9 percent into more detailed cost categories and weights.

TABLE E3--CAPITAL COST SHARE COMPOSITION FOR THE PROPOSED 2017-BASED LTCH MARKET BASKET

	Capital Cost Share Composition Before Lease Expense Allocation (Percent)	Capital Cost Share Composition After Lease Expense Allocation (Percent)
Depreciation	**22**	**56**
Building and Fixed Equipment	17	42
Movable Equipment	5	14
Interest	**8**	**21**
Government/Nonprofit	2	4
For Profit	6	17
Lease	*63*	*N/A*
Other	**7**	**23**

Note: Detail may not add to total due to rounding.

e. Proposed 2017-Based LTCH Market Basket Cost Categories and Weights

Table E4 shows the proposed cost categories and weights for the proposed 2017-based LTCH market basket compared to the 2013-based LTCH market basket.

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TABLE E4--PROPOSED 2017-BASED LTCH MARKET BASKET COST WEIGHTS COMPARED TO 2013-BASED LTCH MARKET BASKET COST WEIGHTS

Cost Category	Proposed 2017-based LTCH Market Basket Cost Weight	2013-based LTCH Market Basket Cost Weight
Total	**100.0**	**100.0**
Compensation	**53.2**	**53.9**
Wages and Salaries	46.4	46.6
Employee Benefits	6.8	7.3
Utilities	**1.9**	**2.2**
Electricity	1.3	1.0
Fuel, Oil, and Gasoline	0.6	1.1
Water & Sewerage	n/a	0.1
Professional Liability Insurance	**0.5**	**0.9**
Malpractice	0.5	0.9
All Other Products and Services	**34.4**	**33.2**
All Other Products	**15.6**	**16.3**
Pharmaceuticals	6.2	7.6
Food: Direct Purchases	1.4	1.8
Food: Contract Services	1.6	1.1
Chemicals	0.5	0.7
Medical Instruments	3.6	2.4
Rubber & Plastics	0.5	0.6
Paper and Printing Products	0.8	1.2
Miscellaneous Products	1.1	0.8
All Other Services	**18.9**	**16.9**
Labor-Related Services	**9.7**	**8.3**
Professional Fees: Labor-related	4.5	3.5
Administrative and Facilities Support Services	0.9	0.9
Installation, Maintenance, and Repair	2.1	2.0
All Other: Labor-related Services	2.3	1.9
Nonlabor-Related Services	**9.1**	**8.6**
Professional Fees: Nonlabor-related	5.9	3.6
Financial services	1.2	2.9
Telephone Services	0.4	0.7
All Other: Nonlabor-related Services	1.6	1.4
Capital-Related Costs	**9.9**	**9.7**
Depreciation	**5.5**	**5.3**
Building and Fixed Equipment	4.2	3.9
Movable Equipment	1.3	1.4
Interest Costs	**2.1**	**2.4**
Government/Nonprofit	0.4	0.5
For Profit	1.6	1.8
Other Capital-Related Costs	**2.3**	**2.0**

Note: Totals may not sum due to rounding.

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4. Selection of Proposed Price Proxies

After developing the proposed cost weights for the 2017-based LTCH market basket, we selected the most appropriate wage and price proxies currently available to represent the rate of price change for each expenditure category. For the majority of the cost weights, we base the price proxies on U.S. 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 NAICS and the occupational ECIs are based on the 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 evaluate the price proxies using the criteria of reliability, timeliness, availability, and relevance:

- *Reliability.* 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.* 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.* 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.
- *Relevance.* Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied.

We believe that the CPIs, PPIs, and ECIs that we have selected 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 E7 lists all price proxies that we propose to use for the 2017-based LTCH market basket. In this section of this rule is a detailed explanation of the price proxies we are proposing for each cost category weight.

a. Price Proxies for the Operating Portion of the Proposed 2017-Based LTCH Market Basket

(1) Wages and Salaries

We propose to continue to use the ECI for Wages and Salaries for All Civilian workers in Hospitals (BLS series code CIU1026220000000I) to measure the wage rate growth of this cost category. This is the same price proxy used in the 2013-based LTCH market basket (81 FR 57092).

(2) Employee Benefits

We propose to continue to use the ECI for Total Benefits for All Civilian workers in Hospitals to measure price growth of this category. This ECI is calculated using the ECI for Total Compensation for All Civilian workers in Hospitals (BLS series code CIU1016220000000I) and the relative importance of wages and salaries within total compensation. This is the same price proxy used in the 2013-based LTCH market basket (81 FR 57092).

(3) Electricity

We propose to continue to use the PPI Commodity Index for Commercial Electric Power (BLS series code WPU0542) to measure the price growth of this cost category. This is the same price proxy used in the 2013-based LTCH market basket (81 FR 57092).

(4) Fuel, Oil, and Gasoline

Similar to the 2013-based LTCH market basket, for the 2017-based LTCH market basket, we propose to use a blend of the PPI Industry for Petroleum Refineries and the PPI Commodity for Natural Gas. Our analysis of the Bureau of Economic Analysis' 2012 Benchmark I–O data (use table before redefinitions, purchaser's value for NAICS 622000 [Hospitals]), shows that Petroleum Refineries expenses account for approximately 90 percent and Natural Gas expenses account for approximately 10 percent of Hospitals' (NAICS 622000) total Fuel, Oil, and Gasoline expenses. Therefore, we propose to use a blend of 90 percent of the PPI Industry for Petroleum Refineries (BLS series code PCU324110324110) and 10 percent of the PPI Commodity Index for Natural Gas (BLS series code WPU0531) as the price proxy for this cost category. The 2013-based LTCH market basket used a 70/30 blend of these price proxies, reflecting the 2007 I–O data (81 FR 57092). We believe that these two price proxies continue to be the most technically appropriate indices available to measure the price growth of the Fuel, Oil, and Gasoline cost category in the 2017-based LTCH market basket.

(5) Professional Liability Insurance

We propose to continue to use the CMS Hospital Professional Liability Index as the price proxy for PLI costs in the proposed 2017-based LTCH market basket. To generate this index, we collect commercial insurance medical liability premiums for a fixed level of coverage while holding non-price factors constant (such as a change in the level of coverage). This is the same proxy used in the 2013-based LTCH market basket (81 FR 57092).

(6) Pharmaceuticals

We propose to continue 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 proxy used in the 2013-based LTCH market basket (81 FR 57092).

(7) Food: Direct Purchases

We propose to continue 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 price proxy used in the 2013-based LTCH market basket (81 FR 57092).

(8) Food: Contract Purchases

We propose to continue to use the CPI for Food Away From Home (BLS series code CUUR0000SEFV) to measure the price growth of this cost category. This is the same proxy used in the 2013-based LTCH market basket (81 FR 57092).

(9) Chemicals

Similar to the 2013-based LTCH market basket, we propose to use a four-part blended PPI as the proxy for the chemical cost category in the 2017-based LTCH market basket. The proposed blend is composed of the PPI Industry for Industrial Gas Manufacturing, Primary Products (BLS series code PCU325120325120P), the PPI Industry for Other Basic Inorganic

Chemical Manufacturing (BLS series code PCU32518–32518–), the PPI Industry for Other Basic Organic Chemical Manufacturing (BLS series code PCU32519–32519–), and the PPI Industry for Other Miscellaneous Chemical Product Manufacturing (BLS series code PCU325998325998). We note that the four part blended PPI used in the 2013-based LTCH market basket is composed of the PPI Industry for Industrial Gas Manufacturing (BLS series code PCU325120325120P), the PPI Industry for Other Basic Inorganic Chemical Manufacturing (BLS series code PCU32518–32518–), the PPI Industry for Other Basic Organic Chemical Manufacturing (BLS series code PCU32519–32519–), and the PPI Industry for Soap and Cleaning Compound Manufacturing (BLS series code PCU32561–32561–). For the 2017-based LTCH market basket, we propose to derive the weights for the PPIs using the 2012 Benchmark I–O data. The 2013-based LTCH market basket used the 2007 Benchmark I–O data to derive the weights for the four PPIs (81 FR 57092). Table E5 shows the weights for each of the four PPIs used to create the proposed blended Chemical proxy for the 2017-based LTCH market basket compared to the 2013-based blended Chemical proxy. We note that in the 2012 I–O data, the share of total chemicals expenses that the Soap and Cleaning Compound Manufacturing (NAICS 325610) represents decreased relative to the 2007 I–O data (from 5 percent to 2 percent), while the share of the total chemicals expenses that the All Other Chemical Product and Preparation manufacturing (NAICS 3259A0) categories represents increased (from 5 percent to 7 percent). As a result, we are proposing to remove the PPI Industry for Soap and Cleaning Compound Manufacturing from the proposed blend for the 2017-based LTCH market basket and replace it with the PPI Industry for Other Miscellaneous Chemical Product Manufacturing.

TABLE E5: BLENDED CHEMICAL PPI WEIGHTS

Name	Proposed 2017-based LTCH Weights (Percent)	2013-based LTCH Weights (Percent)	NAICS
PPI Industry for Industrial Gas Manufacturing	19	32	325120
PPI Industry for Other Basic Inorganic Chemical Manufacturing	13	17	325180
PPI Industry for Other Basic Organic Chemical Manufacturing	60	45	325190
PPI Industry for Soap and Cleaning Compound Manufacturing	n/a	6	325610
PPI Industry for Other Miscellaneous Chemical Product Manufacturing	8	n/a	325998

(10) Medical Instruments

We propose to continue to use a blend of two PPIs for the Medical Instruments cost category. The 2012 Benchmark I–O data shows an approximate 57/43 split between Surgical and Medical Instruments and Medical and Surgical Appliances and Supplies for this cost category. Therefore, we propose a blend composed of 57 percent of the commodity-based PPI Commodity for Surgical and Medical Instruments (BLS series code WPU1562) and 43 percent of the PPI Commodity for Medical and Surgical Appliances and Supplies (BLS series code WPU1563). The 2013-based LTCH market basket used a 50/50 blend of these PPIs based on the 2007 Benchmark I–O data (81 FR 57093).

(11) Rubber and Plastics

We propose to continue 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 proxy used in the 2013-based LTCH market basket (81 FR 57093).

(12) Paper and Printing Products

We propose to continue 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 proxy used in the 2013-based LTCH market basket (81 FR 57093).

(13) Miscellaneous Products

We propose to continue to use the PPI Commodity for Finished Goods Less Food and Energy (BLS series code WPUFD4131) to measure the price growth of this cost category. This is the same proxy used in the 2013-based LTCH market basket (81 FR 57093).

(14) Professional Fees: Labor-Related

We propose to continue 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 proxy used in the 2013-based LTCH market basket (81 FR 57093).

(15) Administrative and Facilities Support Services

We propose to continue 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 proxy used in the 2013-based LTCH market basket (81 FR 57093).

(16) Installation, Maintenance, and Repair Services

We propose to continue 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 cost category. This is the same proxy used in the 2013-based LTCH market basket (81 FR 57093).

(17) All Other: Labor-Related Services

We propose to continue 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 proxy used in the 2013-based LTCH market basket (81 FR 57093).

(18) Professional Fees: Nonlabor-Related

We propose to continue 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 proxy used in the 2013-based LTCH market basket (81 FR 57093).

(19) Financial Services

We propose to continue 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 proxy used in the 2013-based LTCH market basket (81 FR 57093).

(20) Telephone Services

We propose to continue to use the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category. This is the same proxy used in the 2013-based LTCH market basket (81 FR 57093).

(21) All Other: Nonlabor-Related Services

We propose to continue to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. This is the same proxy used in the 2013-based LTCH market basket (81 FR 57093).

b. Price Proxies for the Capital Portion of the Proposed 2017-Based LTCH Market Basket

(1) Capital Price Proxies Prior to Vintage Weighting

We propose to continue to use the same price proxies for the capital-related cost categories as were applied in the 2013-based LTCH market basket, which are provided in Table E7 and described in this section of this rule. Specifically, we propose to proxy:

- *Depreciation:* Building and Fixed Equipment cost category by BEA's Chained Price Index for Nonresidential Construction for Hospitals and Special Care Facilities (BEA Table 5.4.4. Price Indexes for Private Fixed Investment in Structures by Type).
- *Depreciation:* Movable Equipment cost category by the PPI Commodity for Machinery and Equipment (BLS series code WPU11).
- Nonprofit Interest cost category by the average yield on domestic municipal bonds (Bond Buyer 20-bond index).
- For-profit Interest cost category by the average yield on Moody's Aaa bonds (Federal Reserve).
- Other Capital-Related cost category by the CPI–U for Rent of Primary Residence (BLS series code CUUS0000SEHA).

We believe these are the most appropriate proxies for LTCH capital-related costs that meet our selection criteria of relevance, timeliness, availability, and reliability. We are also proposing to continue to vintage weight the capital price proxies for Depreciation and Interest in order to capture the long-term consumption of capital. This vintage weighting method is similar to the method used for the 2013-based LTCH market basket and is described in section VII.D.4.b.(2). of the preamble of this proposed rule.

(2) Vintage Weights for Price Proxies

Because capital is acquired and paid for over time, capital-related expenses in any given year are determined by both past and present purchases of physical and financial capital. The vintage-weighted capital-related portion of the proposed 2017-based LTCH market basket is intended to capture the long-term consumption of capital, using vintage weights for depreciation (physical capital) and interest (financial capital). These vintage weights reflect the proportion of capital-related purchases attributable to each year of the expected life of building and fixed equipment, movable equipment, and interest. We propose to use vintage weights to compute vintage-weighted price changes associated with depreciation and interest expenses.

Capital-related costs are inherently complicated and are determined by complex capital-related purchasing decisions, over time, based on such factors as interest rates and debt financing. In addition, capital is depreciated over time instead of being consumed in the same period it is purchased. By accounting for the vintage nature of capital, we are able to provide an accurate and stable annual measure of price changes. Annual nonvintage price changes for capital are unstable due to the volatility of interest rate changes and, therefore, do not reflect the actual annual price changes for LTCH capital-related costs. The capital-related component of the proposed 2017-based LTCH market basket reflects the underlying stability of the capital-related acquisition process.

The methodology used to calculate the vintage weights for the proposed 2017-based LTCH market basket is the same as that used for the 2013-based LTCH market basket with the only difference being the inclusion of more recent data. To calculate the vintage weights for depreciation and interest expenses, we first need a time series of capital-related purchases for building and fixed equipment and movable equipment. We found no single source that provides an appropriate time series of capital-related purchases by hospitals for all of the previously mentioned components of capital purchases. The early Medicare cost reports did not have sufficient capital-related data to meet this need. Data we obtained from the American Hospital Association (AHA) do not include annual capital-related purchases. However, the AHA does provide a consistent database of total expenses back to 1963. Consequently, we propose to use data from the AHA Panel Survey and the AHA Annual Survey to obtain a time series of total expenses for hospitals. We are also proposing to use data from the AHA Panel Survey supplemented with the ratio of depreciation to total hospital expenses obtained from the Medicare cost reports to derive a trend of annual depreciation expenses for 1963 through 2017. We propose to separate these depreciation expenses into annual amounts of building and fixed equipment depreciation and movable equipment depreciation as previously determined. From these annual depreciation amounts we derive annual end-of-year book values for building and fixed equipment and movable equipment using the expected life for each type of asset category. While data are not available that are specific to LTCHs, we believe this information for all hospitals serves as a reasonable proxy for the pattern of depreciation for LTCHs.

To continue to calculate the vintage weights for depreciation and interest expenses, we also needed to account for the expected lives for building and fixed equipment, movable equipment, and interest for the proposed 2017-based LTCH market basket. We propose to calculate the expected lives using Medicare cost report data for LTCHs. The expected life of any asset can be determined by dividing the value of the asset (excluding fully depreciated assets) by its current year depreciation amount. This calculation yields the estimated expected life of an asset if the rates of depreciation were to continue at current year levels, assuming straight-line depreciation. Using this proposed method, we determined the average expected life of building and fixed equipment to be equal to 18 years, and the average expected life of movable equipment to be equal to 9 years. For the expected life of interest, we believe that vintage weights for interest should represent the average expected life of building and fixed equipment because, based on previous research described in the FY 1997 IPPS final rule (61 FR 46198), the expected life of hospital debt instruments and the expected life of buildings and fixed equipment are similar. We note that for the 2013-based LTCH-specific market basket, we derived an expected average life of building and fixed equipment of 18

years and an expected average life of movable equipment of 8 years (81 FR 57094).

Multiplying these expected lives by the annual depreciation amounts results in annual year-end asset costs for building and fixed equipment and movable equipment. Then we calculated a time series, beginning in 1964, of annual capital purchases by subtracting the previous year's asset costs from the current year's asset costs.

For the building and fixed equipment and movable equipment vintage weights, we propose to use the real annual capital-related purchase amounts for each asset type to capture the actual amount of the physical acquisition, net of the effect of price inflation. These real annual capital-related purchase amounts are produced by deflating the nominal annual purchase amount by the associated price proxy as previously provided. For the interest vintage weights, we propose to use the total nominal annual capital-related purchase amounts to capture the value of the debt instrument (including, but not limited to, mortgages and bonds). Using these capital-related purchase time series specific to each asset type, we propose to calculate the vintage weights for building and fixed equipment, for movable equipment, and for interest.

The vintage weights for each asset type are deemed to represent the average purchase pattern of the asset over its expected life (in the case of building and fixed equipment and interest, 18 years, and in the case of movable equipment, 9 years). For each asset type, we used the time series of annual capital-related purchase amounts available from 2017 back to 1964. These data allow us to derive thirty-seven 18-year periods of capital-related purchases for building and fixed equipment and interest, and forty-six 9-year periods of capital-related purchases for movable equipment. For each 18-year period for building and fixed equipment and interest, or 9-year period for movable equipment, we propose to calculate annual vintage weights by dividing the capital-related purchase amount in any given year by the total amount of purchases over the entire 18-year or 9-year period. This calculation is done for each year in the 18-year or 9-year period and for each of the periods for which we have data. Then we are proposing to calculate the average vintage weight for a given year of the expected life by taking the average of these vintage weights across the multiple periods of data.

The vintage weights for the capital-related portion of the proposed 2017-based LTCH market basket and the 2013-based LTCH market basket are presented in Table E6.

TABLE E6--PROPOSED 2017-BASED LTCH MARKET BASKET AND 2013-BASED LTCH MARKET BASKET VINTAGE WEIGHTS FOR CAPITAL-RELATED PRICE PROXIES

	Building and Fixed Equipment		Movable Equipment		Interest	
Year	2017-based 18 years	2013-based 18 years	2017-based 9 years	2013-based 8 years	2017-based 18 years	2013-based 18 years
1	0.046	0.044	0.093	0.104	0.031	0.029
2	0.047	0.046	0.096	0.110	0.032	0.031
3	0.046	0.048	0.101	0.117	0.033	0.034
4	0.048	0.050	0.109	0.124	0.036	0.037
5	0.048	0.051	0.113	0.128	0.038	0.039
6	0.051	0.051	0.117	0.132	0.042	0.042
7	0.052	0.051	0.119	0.140	0.045	0.043
8	0.053	0.052	0.124	0.145	0.048	0.046
9	0.055	0.053	0.129	--	0.052	0.049
10	0.057	0.056	--	--	0.056	0.054
11	0.058	0.058	--	--	0.059	0.059
12	0.059	0.059	--	--	0.063	0.063
13	0.061	0.061	--	--	0.068	0.068
14	0.062	0.062	--	--	0.072	0.072
15	0.063	0.062	--	--	0.075	0.076
16	0.063	0.063	--	--	0.078	0.080
17	0.064	0.066	--	--	0.083	0.086
18	0.065	0.067	--	--	0.088	0.091
Total	1.000	1.000	1.000	1.000	1.000	1.000

Note: Numbers may not add to total due to rounding.

The process of creating vintage-weighted price proxies requires applying the vintage weights to the price proxy index where the last applied vintage weight in Table E6 is applied to the most recent data point. We have provided on the CMS website an example of how the vintage weighting price proxies are calculated, using example vintage weights and example price indices. The example can be found at the following link: *http://*

www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html in the zip file titled ''Weight Calculations as described in the IPPS FY 2010 Proposed Rule.''

c. Summary of Price Proxies of the Proposed 2017-Based LTCH Market Basket

Table E7 shows both the operating and capital price proxies for the proposed 2017-based LTCH market basket.

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TABLE E7—PROPOSED PRICE PROXIES FOR THE PROPOSED 2017-BASED LTCH MARKET BASKET

Cost Description	Price Proxies
Total	
Compensation	
Wages and Salaries	ECI for Wages and Salaries for All Civilian workers in Hospitals
Employee Benefits	ECI for Total Benefits for All Civilian workers in Hospitals
Utilities	
Electricity	PPI for Commercial Electric Power
Fuel, Oil, and Gasoline	Blend of the PPI for Petroleum Refineries and PPI for Natural Gas
Professional Liability Insurance	
Malpractice	CMS Hospital Professional Liability Insurance Premium Index
All Other Products and Services	
All Other Products	
Pharmaceuticals	PPI Commodity for Pharmaceuticals for human use, prescription
Food: Direct Purchases	PPI for Processed Foods and Feeds
Food: Contract Services	CPI-U for Food Away From Home
Chemicals	Blend of Chemical PPIs
Medical Instruments	Blend of the PPI for Surgical and medical instruments and PPI for Medical and surgical appliances and supplies
Rubber & Plastics	PPI Commodity for Rubber and Plastic Products
Paper and Printing Products	PPI Commodity for Converted Paper and Paperboard Products
Miscellaneous Products	PPI Commodity for Finished Goods Less Food and Energy
All Other Services	
Labor-Related Services	
Professional Fees: Labor-related	ECI for Total compensation for Private industry workers in Professional and related
Administrative and Facilities Support Services	ECI for Total compensation for Private industry workers in Office and administrative support
Installation, Maintenance, and Repair	ECI for Total compensation for Civilian workers in Installation, maintenance, and repair
All Other: Labor-related Services	ECI for Total compensation for Private industry workers in Service occupations
Nonlabor-Related Services	
Professional Fees: Nonlabor-related	ECI for Total compensation for Private industry workers in Professional and related
Financial services	ECI for Total compensation for Private industry workers in Financial activities
Telephone Services	CPI-U for Telephone Services
All Other: Nonlabor-related Services	CPI-U for All Items Less Food and Energy
Capital-Related Costs	
Depreciation	
Building and Fixed Equipment	BEA chained price index for nonresidential construction for hospitals and special care facilities - vintage weighted (18 years)
Movable Equipment	PPI Commodity for machinery and equipment - vintage weighted (9 years)
Interest Costs	
Government/Nonprofit	Average yield on domestic municipal bonds (Bond Buyer 20 bonds) - vintage weighted (18 years)
For Profit	Average yield on Moody's Aaa bonds - vintage weighted (18 years)
Other Capital-Related Costs	CPI-U for Rent of primary residence

Note: Totals may not sum to 100.0 percent due to rounding

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5. Proposed FY 2021 Market Basket Update for LTCHs

For FY 2021 (that is, October 1, 2020 through September 30, 2021), we propose to use an estimate of the proposed 2017-based LTCH market basket to update payments to LTCHs based on the best available data. Consistent with historical practice, we estimate the LTCH market basket update for the LTCH PPS based on IHS Global, Inc.'s (IGI's) forecast using the most recent available data. IGI is a nationally recognized economic and financial forecasting firm with which we contract to forecast the components of the market baskets and multifactor productivity (MFP).

Based on IGI's fourth quarter 2019 forecast with history through the third quarter of 2019, the projected market basket update for FY 2021 is 2.9 percent. Therefore, consistent with our historical practice of estimating market basket increases based on the best available data, we are proposing a market basket update of 2.9 percent for FY 2021. Furthermore, because the proposed FY 2021 annual update is based on the most recent market basket estimate for the 12-month period (currently 2.9 percent), we also are proposing that if more recent data become subsequently available (for example, a more recent estimate of the market basket), we would use such data, if appropriate, to determine the FY 2021 annual update in the final rule. (The proposed annual update to the LTCH PPS standard payment rate for FY 2021 is discussed in greater detail in section V.A.2. of the Addendum to this proposed rule.)

Using the current 2013-based LTCH market basket and IGI's fourth quarter 2019 forecast for the market basket components, the FY 2021 market basket update would be 3.0 percent (before taking into account any statutory adjustment). Therefore, the update based on the proposed 2017-based LTCH market basket is currently 0.1 percentage point lower. This lower update is primarily due to the lower Pharmaceuticals cost weight in the proposed 2017-based market basket (6.2 percent) compared to the 2013-based LTCH market basket (7.6 percent). This is partially offset by the higher cost weights associated with All Other Services (such as Professional Fees and Installation, Maintenance, and Repair Services) for the proposed 2017-based LTCH market basket relative to the 2013-based LTCH market basket. Table E8 compares the proposed 2017-based LTCH market basket and the 2013-based LTCH market basket percent changes.

TABLE E8—PROPOSED 2017-BASED LTCH MARKET BASKET AND 2013-BASED LTCH MARKET BASKET PERCENT CHANGES, FYs 2016 THROUGH 2023

	Fiscal Year (FY)	Proposed 2017-Based LTCH Market Basket Index Percent Change	2013-Based LTCH Market Basket Index Percent Change
Historical Data	FY 2016	1.8	1.9
	FY 2017	2.4	2.6
	FY 2018	2.4	2.5
	FY 2019	2.3	2.3
	Average 2016-2019	**2.2**	**2.3**
Forecast	FY 2020	2.5	2.5
	FY 2021	2.9	3.0
	FY 2022	3.1	3.2
	FY 2023	3.1	3.2
	Average 2020-2023	**2.9**	**3.0**

Note that these market basket percent changes do not include any further adjustments as may be statutorily required.

Source: IHS Global Inc. 4th quarter 2019 forecast

Over the time period covering FY 2016 through FY 2019, the average growth rate of the proposed 2017-based LTCH market basket is roughly 0.1 percentage point lower than the 2013-based LTCH market basket. The lower growth rate is primarily a result of the lower Pharmaceuticals cost weight in the proposed 2017-based market basket compared to the 2013-based LTCH market basket. Historically, the price growth of pharmaceutical costs has exceeded the price growth rates for most of the other market basket cost categories. Therefore, a lower Pharmaceuticals cost weight would, all else equal, result in a lower market basket update. As previously stated, the Pharmaceuticals cost weights for the proposed 2017-based LTCH market basket and the 2013-based LTCH market basket are based on the 2017 and 2013 Medicare cost report data for LTCHs, respectively.

6. Proposed FY 2021 Labor-Related Share

As discussed in section V.B. of the Addendum to this proposed rule, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS payments to account for differences in LTCH area wage levels (§ 412.525(c)). The labor-related portion of the LTCH PPS standard Federal payment rate, hereafter referred to as the

labor-related share, is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. 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. As discussed in more detail in this section of this rule and similar to the 2013-based LTCH market basket, we classify a cost category as labor-related and include it in the labor-related share if the cost category is defined as being labor-intensive and its cost varies with the local labor market. As stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42642), the labor-related share for FY 2020 was defined as the sum of the FY 2020 relative importance of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related Services; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related Services; and a portion of the Capital-Related Costs from the 2013-based LTCH market basket.

We propose to continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market. Given this, based on our definition of the labor-related share and the cost categories in the proposed 2017-based LTCH market basket, we propose to include in the labor-related share for FY 2021 the sum of the FY 2021 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 cost weight from the proposed 2017-based LTCH market basket.

Similar to the 2013-based LTCH market basket, the proposed 2017-based LTCH market basket includes two cost categories for nonmedical Professional fees (including but not limited to, expenses for legal, accounting, and engineering services). These are Professional Fees: Labor-related and Professional Fees: Nonlabor-related. For the proposed 2017-based LTCH market basket, we propose to estimate the labor-related percentage of non-medical professional fees (and assign these expenses to the Professional Fees: Labor-related services cost category) based on the same method that was used to determine the labor-related percentage of professional fees in the 2013-based LTCH market basket.

As was done for the 2013-based LTCH market basket, we propose to determine the proportion of legal, accounting and auditing, engineering, and management consulting services that meet our definition of labor-related services based on a survey of hospitals conducted by CMS in 2008. We notified the public of our intent to conduct this survey on December 9, 2005 (70 FR 73250) and did not receive any public comments in response to the notice (71 FR 8588). A discussion of the composition of the survey and post-stratification can be found in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43850 through 43856). Based on the weighted results of the survey, we determined that hospitals purchase, on average, the following portions of contracted professional services outside of their local labor market:

- 34 percent of accounting and auditing services.
- 30 percent of engineering services.
- 33 percent of legal services.
- 42 percent of management consulting services.

For the proposed 2017-based LTCH market basket, we propose to apply each of these percentages to the respective 2012 Benchmark I–O cost category underlying the professional fees cost category to determine the Professional Fees: Nonlabor-related costs. The Professional Fees: Labor-related costs were determined to be the difference between the total costs for each Benchmark I–O category and the Professional Fees: Nonlabor-related costs. This is the same methodology that we used to separate the 2013-based LTCH market basket professional fees category into Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories.

In the proposed 2017-based LTCH market basket, nonmedical professional fees that were subject to allocation based on these survey results represent approximately 5.6 percent of total costs (and are limited to those fees related to Accounting & Auditing, Legal, Engineering, and Management Consulting services). Based on our survey results, we propose to apportion approximately 3.6 percentage points of the 5.6 percentage point figure into the Professional Fees: Labor-related share cost category and designate the remaining approximately 2.0 percentage points into the Professional Fees: Nonlabor-related cost category.

In addition to the professional services as previously listed, for the 2017-based LTCH market basket, we propose 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 propose 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 2013-based LTCH market basket, we propose for the 2017-based LTCH market basket to use the Medicare cost reports for LTCHs to determine the home office labor-related percentages. The Medicare cost report requires a hospital to report information regarding their home office provider. Using information on the Medicare cost report, we compare the location of the LTCH with the location of the LTCH's home office. We propose to classify a LTCH with a home office located in their respective labor market if the LTCH 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 LTCHs that had home offices located in their respective local labor markets of total Home Office/Related Organization Contract Labor costs for LTCHs with a home office. We determined a LTCH's and its home office's MSA using their zip code information from the Medicare cost report. Using this methodology, we determined that 4 percent of LTCHs' Home Office/Related Organization Contract Labor costs were for home offices located in their respective local labor markets. Therefore, we are allocating 4 percent of the Home Office/Related Organization Contract Labor cost weight (0.1 percentage point = 1.9 percent × 4 percent) to the Professional Fees: Labor-related cost weight and 96 percent of the Home Office/Related Organization Contract Labor cost weight to the Professional Fees: Nonlabor-related cost weight (1.8 percentage points = 1.9 percent × 96 percent). For the 2013-based LTCH market basket, we used a similar methodology but we relied on provider counts rather than Home Office/Related Organization Contract Labor costs to determine the labor-related percentage.

In summary, based on the two allocations mentioned earlier, we apportioned 3.7 percentage points of the professional fees and Home Office/Related Organization Contract Labor 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 0.8 percentage point of total costs) resulting in a Professional Fees: Labor-Related cost weight of 4.5 percent.

As previously stated, we propose to include in the labor-related share the sum of the 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 cost weight from the proposed 2017-based LTCH market basket. The relative importance reflects the different rates of price change for these cost categories between the base year (2017) and FY 2021. Based on IGI's fourth quarter 2019 forecast of the proposed 2017-based LTCH market basket, the sum of the FY 2021 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 63.6 percent. The portion of Capital costs that is influenced by the local labor market is estimated to be 46 percent, which is the same percentage applied to the 2013-based LTCH market basket. Since the relative importance for Capital is 9.5 percent of the proposed 2017-based LTCH market basket in FY 2021, we took 46 percent of 9.5 percent to determine the proposed labor-related share of Capital for FY 2021 of 4.4 percent. Therefore, we are proposing a total labor-related share for FY 2021 of 68.0 percent (the sum of 63.6 percent for the operating cost and 4.4 percent for the labor-related share of Capital). Table E9 shows the FY 2021 labor-related share using the proposed 2017-based LTCH market basket relative importance and the FY 2020 labor-related share using the 2013-based LTCH market basket.

TABLE E9--PROPOSED FY 2021 LTCH LABOR-RELATED SHARE AND FY 2020 LTCH LABOR-RELATED SHARE

	FY 2021 Proposed Labor-related Share based on Proposed 2017-based LTCH Market Basket[1]	FY 2020 Final Labor-related Share based on 2013-based LTCH Market Basket[2]
Wages and Salaries	46.9	46.6
Employee Benefits	6.8	7.2
Professional Fees: Labor-related[3]	4.5	3.4
Administrative and Facilities Support Services	1.0	0.9
Installation, Maintenance, and Repair Services	2.1	2.1
All Other: Labor-related Services	2.3	2.0
Subtotal	**63.6**	**62.2**
Labor-related portion of capital (46%)	4.4	4.1
Total Labor-Related Share	**68.0**	**66.3**

[1] IHS Global Inc. 4th quarter 2019 forecast.

[2]Based on IHS Global Inc. 2nd quarter 2019 forecast as published in the August 16, 2019 **Federal Register** (84 FR 42642).

[3]Includes all contract advertising and marketing costs and a portion of accounting, architectural, engineering, legal, management consulting, and home office/related organization contract labor costs.

The total difference between the FY 2021 labor-related share using the 2017-based LTCH market basket and the FY 2020 labor-related share using the 2013-based LTCH market basket is 1.7 percentage points (68.0 percent and 66.3 percent, respectively). This difference is attributable to: (1) Revision to the base year cost weights (0.8 percentage point); (2) revision to starting point of calculation of relative importance (base year) from 2013 to 2017 (0.6 percentage point); and (3) using an updated IGI forecast and reflecting an additional year of inflation (0.3 percentage point). The 0.8-percentage point difference in the base year cost weights is primarily due to the incorporation of the 2012 I–O data which shows an increase in the Professional Fees: Labor-Related services.

We note that the use of the Medicare cost report to derive the Home Office/Related Organization Contract Labor cost weight has −0.1 percentage point impact, meaning if we were to use the I–O data to derive the Home Office/Related Organization Contract Labor cost weight, the labor-related share would be 0.1 percentage point higher. The impact of using the Medicare cost report data to calculate the Home Office/Related Organization Contract Labor cost weight is minimal because if we were to instead use the I–O data to derive this weight, it would also increase the residual ''All Other'' cost weight from 28.3 percent (using the Medicare cost report data to calculate the Home Office/Related Organization Contract Labor cost weight) to 30.2 percent (using the I–O data to calculate the Home Office/Related Organization Contract labor cost weight). The higher residual ''All Other'' cost weight then leads to relatively higher cost weight for Administrative and Facilities Support Services which is also reflected in the labor-related share.

VIII. Quality Data Reporting Requirements for Specific Providers and Suppliers

In section VIII. of the preamble of this proposed rule, we discuss the following Medicare quality reporting systems:

- In section VIII.A., the Hospital IQR Program;
- In section VIII.B., the PCHQR Program; and
- In section VIII.C., the LTCH QRP.

In addition, in section VIII.D. of the preamble of this proposed rule, we are proposing changes to the Medicare and Medicaid Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs) for eligible hospitals and critical access hospitals (CAHs).

A. Hospital Inpatient Quality Reporting (IQR) Program

1. Background and History of the Hospital IQR Program

The Hospital IQR Program strives to put patients first by 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 CMS programs. In combination with other efforts across the Department of Health and Human Services, we believe the Hospital IQR Program incentivizes hospitals to improve healthcare quality and value, while giving patients the tools and information needed to make the best decisions for themselves.

We seek to promote higher quality and more efficient healthcare for Medicare beneficiaries. This effort is supported by the adoption of widely-agreed upon quality and cost measures. We have worked with relevant stakeholders to define measures in almost every care setting and currently measure some aspect of care for almost all Medicare beneficiaries. These measures assess clinical processes, patient safety and adverse events, patient experiences with care, care coordination, and clinical outcomes, as well as cost of care. We have implemented quality measure reporting programs for multiple settings of care. To measure the quality of hospital inpatient services, we implemented the Hospital IQR Program, previously referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program. We refer readers to the FY 2010 IPPS/LTCH PPS final rule (74 FR 43860 through 43861) and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181) for detailed discussions of the history of the Hospital IQR Program, including the statutory history, and to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57148 through 57150), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38326 through 38328 and 82 FR 38348), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41609), and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42509) for the measures we have previously adopted for the Hospital IQR Program measure set for the FY 2022 payment determination and subsequent years. We also refer readers to 42 CFR 412.140 for Hospital IQR Program regulations.

2. Retention of Previously Adopted Hospital IQR Program Measures for Subsequent Payment Determinations

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53512 through 53513) for our finalized measure retention policy. We are not proposing any changes to this policy in this proposed rule.

3. Removal Factors for Hospital IQR Program Measures

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41540 through 41544) for a summary of the Hospital IQR Program's removal factors.

We are not proposing any changes to our policies regarding measure removal in this proposed rule.

4. Considerations in Expanding and Updating Quality Measures

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53510 through 53512) for a discussion of the previous considerations we have used to expand and update quality measures under the Hospital IQR Program. We also refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41147 through 41148), in which we describe the Meaningful Measures Initiative, our objectives under this framework for quality measurement, and the quality topics that we have identified as high impact measurement areas that are relevant and meaningful to both patients and providers. We are not proposing any changes to these policies in this proposed rule.

5. Proposed New Measures for the Hospital IQR Program Measure Set

We are not proposing to adopt any new measures in this proposed rule.

6. Summary of Previously Finalized Hospital IQR Program Measures for the FY 2022 Payment Determination

This table summarizes the previously finalized Hospital IQR Program Measures for the FY 2022 Payment Determination:

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Measures for the FY 2022 Payment Determination		
Short Name	**Measure Name**	**NQF #**
National Healthcare Safety Network Measures		
HCP	Influenza Vaccination Coverage Among Healthcare Personnel	0431
Claims-Based Patient Safety Measures		
COMP-HIP-KNEE *++	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	1550
CMS PSI 04	CMS Death Rate among Surgical Inpatients with Serious Treatable Complications	+
Claims-Based Mortality Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized-Mortality Rate Following Acute Ischemic Stroke	N/A
Claims-Based Coordination of Care Measures		
READM-30-HWR	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episodeof-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	N/A
Chart-Abstracted Clinical Process of Care Measures		
PC-01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs)		
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC-05	Exclusive Breast Milk Feeding	0480
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Patient Experience of Care Survey Measures		
HCAHPS***	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)

* Finalized for removal from the Hospital IQR Program beginning with the FY 2023 payment determination, as discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41558 through 41559).

*** In the CY 2019 OPPS/ASC PPS final rule with comment period (83 FR 59140 through 59149), we finalized removal of the Communication About Pain questions from the HCAHPS Survey effective with October 2019 discharges, for the FY 2021 payment determination and subsequent years.

+ Measure is no longer endorsed by the NQF but was endorsed at time of adoption. Section 1886(b)(3)(B)(viii)(IX)(bb) 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 inpatient setting.

++ We have updated the short name for the Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) measure (NQF #1550) measure from Hip/Knee Complications to COMP-HIP-KNEE in order to maintain consistency with the updated Measure ID and hospital reports for the *Hospital Compare* and/or its successor website.

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7. Summary of Previously Finalized Hospital IQR Program Measures for the FY 2023 Payment Determination

This table summarizes the previously finalized Hospital IQR Program measure set for the FY 2023 Payment Determination:

BILLING CODE 4120–01–P

Measures for the FY 2023 Payment Determination		
Short Name	**Measure Name**	**NQF #**
National Healthcare Safety Network Measures		
HCP	Influenza Vaccination Coverage Among Healthcare Personnel	0431
Claims-Based Patient Safety Measures		
CMS PSI 04	CMS Death Rate among Surgical Inpatients with Serious Treatable Complications	–
Claims-Based Mortality Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized-Mortality Rate Following Acute Ischemic Stroke	N/A
Claims-Based Coordination of Care Measures		
READM-30-HWR*	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	N/A
Chart-Abstracted Clinical Process of Care Measures		
PC-01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC-05	Exclusive Breast Milk Feeding	0480
Safe Use of Opioids***	Safe Use of Opioids – Concurrent Prescribing	3316e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)

* In the FY 2020 IPPS/LTCH PPS final rule, we finalized our proposal to remove the claims-only Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF #1789) and to replace it with the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879) (Hybrid HWR measure), beginning with the FY 2026 payment determination (84 FR 42465 through 42481). The removal of the HWR claims-only measure was contingent on our finalizing our proposal to adopt the Hybrid HWR measure. We finalized our proposal to align the removal of the HWR claims only measure such that its removal aligns with the end of the finalized 2-year voluntary reporting period and the beginning of the finalized mandatory data submission and public reporting of the Hybrid HWR measure.

*** Finalized in the FY 2020 IPPS/LTCH PPS final rule to add to the eCQM measure subset, beginning with the CY 2021 reporting period/FY 2023 payment determination with a clarification and update (84 FR 42449 through 42459).

– Measure is no longer endorsed by the NQF but was endorsed at time of adoption. Section 1886(b)(3)(B)(viii)(IX)(bb) 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 inpatient setting.

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8. Summary of Previously Finalized Hospital IQR Program Measures for the FY 2024 Payment Determination and Subsequent Years

This table summarizes the previously finalized Hospital IQR Program measure set for the FY 2024 Payment Determination and Subsequent Years:

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Measures for the FY 2024 Payment Determination and Subsequent Years *		
Short Name	**Measure Name**	**NQF #**
National Healthcare Safety Network Measures		
HCP	Influenza Vaccination Coverage Among Healthcare Personnel	0431
Claims-Based Patient Safety Measures		
CMS PSI 04	CMS Death Rate among Surgical Inpatients with Serious Treatable Complications	[+]
Claims-Based Mortality Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized-Mortality Rate Following Acute Ischemic Stroke	N/A
Claims-Based Coordination of Care Measures		
READM-30-HWR*	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	N/A
Chart-Abstracted Clinical Process of Care Measures		
PC-01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC-05	Exclusive Breast Milk Feeding	0480
Safe Use of Opioids **	Safe Use of Opioids – Concurrent Prescribing	3316e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)

* In the FY 2020 IPPS/LTCH PPS final rule, we removed the claims-only Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (NQF #1789) and replaced it with the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879) (Hybrid HWR measure), beginning with the FY 2026 payment determination (84 FR 42465 through 42481). The removal of the HWR claims-only measure was contingent on our finalizing our proposal to adopt the Hybrid HWR measure. We finalized our proposal to align the removal of the HWR claims only measure such that its removal aligns with the end of the finalized 2-year voluntary reporting period and the beginning of the finalized mandatory data submission and public reporting of the Hybrid HWR measure.

** Reporting on the Safe Use of Opioids measure is mandatory for the FY 2024 payment determination.

[+] Measure is no longer endorsed by the NQF but was endorsed at time of adoption. Section 1886(b)(3)(B)(viii)(IX)(bb) 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 inpatient setting.

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9. Form, Manner, and Timing of Quality Data Submission

a. Background

Sections 1886(b)(3)(B)(viii)(I) and (b)(3)(B)(viii)(II) of the Act state that the applicable percentage increase for FY 2015 and each subsequent year shall be reduced by one-quarter of such applicable percentage increase (determined without regard to sections 1886(b)(3)(B)(ix), (xi), or (xii) of the Act) for any subsection (d) hospital that does not submit data required to be submitted on measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. In order to successfully participate in the Hospital IQR Program, hospitals must meet specific procedural, data collection, submission, and validation requirements. Previously, the applicable percentage increase for FY 2007 and each subsequent fiscal year until FY 2015 was reduced by 2.0 percentage points for subsection (d) hospitals failing to submit data in accordance with the previously discussed description. In accordance with the statute, the FY 2021 payment determination will begin the seventh year that the Hospital IQR Program will reduce the applicable percentage increase by one-quarter of such applicable percentage increase.

b. Maintenance of Technical Specifications for Quality Measures

For each Hospital IQR Program payment determination, we require that hospitals submit data on each specified measure in accordance with the measure's specifications for a particular period of time. We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538) in which we summarized how the Hospital IQR Program maintains the technical measure specifications for quality measures and the subregulatory process for incorporation of nonsubstantive updates to the measure specifications to ensure that measures remain up-to-date. We are not proposing any changes to these policies in this proposed rule.

The data submission requirements, Specifications Manual, and submission deadlines are posted on the QualityNet website at: *http://www.QualityNet.org/ (and any other successor CMS-designated websites).* The technical specifications used for electronic clinical quality measures (eCQMs) are contained in the CMS Annual Update for the Hospital Quality Reporting Programs (Annual Update). We 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 electronic health record (EHR) vendors to use in order to collect and submit data on eCQMs from hospital EHRs. The Annual Update and implementation guidance documents are available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website at: *https://ecqi.healthit.gov/*. For example, for the CY 2020 reporting period/FY 2022 payment determination, hospitals submitted eCQM data using the May 2019 Annual Update and any applicable addenda.

Hospitals must register and submit quality data through the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System). There are safeguards in place in accordance with the HIPAA Privacy and Security Rules to protect patient information submitted through this website. See 45 CFR parts 160 and 164, subparts A, C, and E.

c. Procedural Requirements

The Hospital IQR Program's procedural requirements are codified in regulation at 42 CFR 412.140. We refer readers to these codified regulations for participation requirements, as further explained by the FY 2014 IPPS/LTCH PPS final rule (78 FR 50810 through 50811) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57168). We are not proposing any changes to these procedural requirements in this proposed rule.

d. Data Submission Requirements for Chart-Abstracted Measures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51640 through 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53536 through 53537), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50811) for details on the Hospital IQR Program data submission requirements for chart-abstracted measures. We are not proposing any changes to the data submission requirements for chart-abstracted measures in this proposed rule.

e. Reporting and Submission Requirements for eCQMs

(1) Background

For a discussion of our previously finalized reporting and submission requirements for eCQMs, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50807 through 50810; 50811 through 50819), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50241 through 50253; 50256 through 50259; and 50273 through 50276), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49692 through 49698; and 49704 through 49709), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57150 through 57161; and 57169 through 57172), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38355 through 38361; 38386 through 38394; 38474 through 38485; and 38487 through 38493), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41567 through 41575; 83 FR 41602 through 41607), and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42501 through 42506).

Current reporting and submission requirements were established in the FY 2018 IPPS/LTCH PPS final rule. In that final rule (82 FR 38368 through 38361), we finalized eCQM reporting and submission requirements such that hospitals were required to report only one, self-selected calendar quarter of data for four self-selected eCQMs for the CY 2018 reporting period/FY 2020 payment determination. Those reporting requirements were extended to the CY 2019 reporting period/FY 2021 payment determination in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41603 through 41604), as well as to the CY 2020 reporting period/FY 2022 payment determination and the CY 2021 reporting period/FY 2023 payment determination in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42501 through 42503).

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42503 through 42505), we also finalized that for the CY 2022 reporting period/FY 2024 payment determination, hospitals would be required to report one, self-selected calendar quarter of data for: (a) Three self-selected eCQMs, and (b) the Safe Use of Opioids—Concurrent Prescribing eCQM (Safe Use eCQM), for a total of four eCQMs.

In this proposed rule, we are proposing to progressively increase, over a 3-year period, the number of quarters for which hospitals are required to report eCQM data, from the current requirement of one self-selected quarter of data to four quarters of data. We believe that increasing the number of quarters for which hospitals are required to report eCQM data will produce more comprehensive and reliable quality measure data for patients and providers. 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.

The current policy requiring more limited reporting was established due to stakeholder feedback about challenges in reporting data, and to give hospitals more time to gain experience with reporting (including upgrading systems and training to support e-CQM reporting) (82 FR 78355 through 78361). That policy, as well as the changes we propose in this proposed rule, are consistent with CMS's stated goal to create a gradual shift to more robust e-CQM reporting (82 FR 38356). Taking an incremental approach over a 3-year period would give hospitals and their vendors time to plan in advance and build upon and utilize investments already made in their EHR infrastructure. We refer readers to section XI.B.7. of the preamble of this proposed rule for a discussion of the increased collection of information burden associated with this proposal. We also refer readers to section VIII.D. of the preamble of this proposed rule for similar proposals under the Promoting Interoperability Program.

(2) Proposed Reporting and Submission Requirements for eCQMs for the CY 2021 Reporting Period/FY 2023 Payment Determination

For the CY 2021 reporting period/FY 2023 payment determination, we propose to increase the amount of data required while keeping the number of eCQMs required the same. Specifically, in this proposed rule, we are proposing that hospitals report two self-selected calendar quarters of data for each of the four self-selected eCQMs for the CY 2021 reporting period/FY 2023 payment determination.

(3) Proposed Reporting and Submission Requirements for eCQMs for the CY 2022 Reporting Period/FY 2024 Payment Determination

For the CY 2022 reporting period/FY 2024 payment determination, we propose to increase the amount of data required while keeping the number and type of eCQMs required the same. Specifically, in this proposed rule, we are proposing to require that hospitals report three self-selected calendar quarters of data for the CY 2022 reporting period/FY 2024 payment determination for each required eCQM: (a) Three self-selected eCQMs; and (b) the Safe Use of Opioids eCQM.

(4) Proposed Reporting and Submission Requirements for eCQMs for the CY 2023 Reporting Period/FY 2025 Payment Determination and Subsequent Years

For the CY 2023 reporting period/FY 2025 payment determination and beyond, we propose to further increase the amount of data required while keeping the number and type of eCQMs required the same. Specifically, in this proposed rule, we are proposing to require that hospitals report four calendar quarters of data beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years for each required eCQM: (a) Three self-selected eCQMs; and (b) the Safe Use of Opioids eCQM.

(5) Continuation of Certification Requirements for eCQM Reporting

(a) Requiring Use of 2015 Edition Certification Criteria

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41604 through 41607), to align the Hospital IQR Program with the Promoting Interoperability Program, we finalized a policy to require hospitals to use the 2015 Edition certification criteria for certified EHR technology (CEHRT) for the CY 2019 reporting period/FY 2021 payment determination and subsequent years. We are not proposing any changes to this policy in this proposed rule.

(b) Requiring EHR Technology To Be Certified to All Available eCQMs

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42505 through 42506), we finalized the requirement that EHRs be certified to all available eCQMs used in the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination and subsequent years. We are not proposing any changes to this policy in this proposed rule.

(6) File Format for EHR Data, Zero Denominator Declarations, and Case Threshold Exemptions

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57169 through 57170) for our previously adopted eCQM file format requirements. Under these requirements, hospitals: (1) Must submit eCQM data via the Quality Reporting Document Architecture Category I (QRDA I) file format as was previously required; (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 files. Hospitals can continue to meet the reporting requirements by submitting data via QRDA I files, zero denominator declaration, or case threshold exemption (82 FR 38387).

More specifically regarding the use of QRDA I files, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57169 through 57170), we stated that we expect QRDA I files to reflect data for one patient per file per quarter, and that they contain the following four key elements that are utilized to identify the file:

- CMS Certification Number (CCN).
- CMS Program Name.
- EHR Patient ID.
- Reporting period specified in the Reporting Parameters Section per the CMS Implementation Guide for the applicable reporting year, which is published on the eCQI Resource Center website at *https://ecqi.healthit.gov/QRDA*.

In this proposed rule, we are proposing to add EHR Submitter ID to the four key elements listed, as previously discussed, as a fifth key element for file identification beginning with the CY 2021 reporting period/FY 2023 payment determination. An EHR Submitter ID is the ID that is assigned by QualityNet to submitter entities upon registering into the system and will be used to upload QRDA I files. For vendors, the EHR Submitter ID is the Vendor ID; for hospitals, the EHR, Submitter ID is the hospital's CCN. Particularly for situations when a hospital uses one or more vendors to submit QRDA I files via the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System), this additional element would prevent the risk of a previously submitted file by a different vendor unintentionally being overwritten. Therefore, hospitals would be required to submit the following elements to identify the QRDA 1 file:

- CMS Certification Number (CCN).
- CMS Program Name.
- EHR Patient ID.
- Reporting period specified in the Reporting Parameters Section.
- EHR Submitter ID.

(7) Submission Deadlines for eCQM Data

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50256 through 50259), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49709), and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57169 through 57172) for our previously adopted policies to align eCQM data reporting periods and submission deadlines for both the Hospital IQR and Medicare

Promoting Interoperability Programs. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57172), we finalized the alignment of the Hospital IQR Program eCQM submission deadline with that of the Medicare Promoting Interoperability Program—the end of 2 months following the close of the calendar year—for the CY 2017 reporting period/FY 2019 payment determination and subsequent years. We note the submission deadline may be moved to the next business day if it falls on a weekend or federal holiday. We are not proposing any changes to the eCQM submission deadlines in this proposed rule.

f. Data Submission and Reporting Requirements for Hybrid Measures

(1) Background

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38350 through 38355), we finalized voluntary reporting of the Hybrid Hospital-Wide Readmission (HWR) measure for the CY 2018 reporting period. For data submission and reporting requirements under the 2018 Voluntary Reporting Period, we finalized that the 13 core clinical data elements and six linking variables for the Hybrid HWR measure be submitted using the QRDA I file format, and that hospitals voluntarily reporting data for the Hybrid HWR measure could use EHR technology certified to the 2014 Edition, the 2015 Edition, or a combination thereof (82 FR 38394 through 38397). In the FY 2020 IPPS/LTCH PPS final rule, we finalized the adoption of the Hybrid HWR measure for the Hospital IQR Program (84 FR 42465 through 42481) as well as a number of requirements related to data submission and reporting requirements for hybrid measures under the Hospital IQR Program (84 FR 42506 through 42508). We adopted the Hybrid HWR measure into the Hospital IQR Program in a stepwise fashion, first accepting data submissions for the Hybrid HWR measure during two voluntary reporting periods (84 FR 42479). Beginning with the FY 2026 payment determination, hospitals are required to report on this measure (84 FR 42479).

(2) Certification and File Format Requirements

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42507), we finalized a requirement that hospitals use EHR technology certified to the 2015 Edition to submit data on the Hybrid HWR measure. In addition, we finalized that the core clinical data elements and linking variables identified in hybrid measure specifications must be submitted using the QRDA I file format. In order to ensure that the data have been appropriately connected to the encounter, the core clinical data elements specified for risk adjustment need to be captured in relation to the start of an inpatient encounter. The QRDA I file standard enables the creation of an individual patient-level quality report that contains quality data for one patient for one or more quality measures.

In this proposed rule, we are proposing to continue the policy that requires hospitals to use EHR technology certified to the 2015 Edition to submit data on the Hybrid HWR measure and expand this requirement to apply to any future hybrid measure adopted into the Hospital IQR Program's measure set. We are also clarifying that core clinical data elements and linking variables must be submitted using the QRDA I file format for future hybrid measures in the program. We are inviting public comment on our proposals.

(3) Additional Submission Requirements

In the FY 2020 IPPS/LTCH PPS final rule, we finalized allowing hospitals to meet the hybrid measure reporting and submission requirements by submitting any combination of data via QRDA I files, zero denominator declarations, and/or case threshold exemptions (84 FR 42507). We also finalized applying similar zero denominator declaration and case threshold exemption policies to hybrid measure reporting as we allow for eCQM reporting (84 FR 42507 through 42508). We are not proposing any changes to the hybrid measure reporting and submission requirement supporting any combination of data via QRDA I files, zero denominator declaration, and/or case threshold exemptions in this proposed rule.

As with eCQM reporting, we encourage all hospitals and their health IT vendors to submit QRDA I files early, and to use one of the pre-submission testing tools for electronic reporting, such as the CMS Pre-Submission Validation Application (PSVA) tool (81 FR 57113), to allow additional time for testing and to make sure all required data files are successfully submitted by the deadline.

(4) Submission Deadlines for Hybrid Measures

We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42508), where we finalized submission deadlines for hybrid measures. We are not proposing any changes to these policies in this proposed rule.

g. Sampling and Case Thresholds for Chart-Abstracted Measures

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50221), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49709) for details on our sampling and case thresholds for the FY 2016 payment determination and subsequent years. We are not proposing any changes to this policy in this proposed rule.

h. HCAHPS Administration and Submission Requirements

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641 through 51643), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537 through 53538), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819 through 50820) for details on previously-adopted HCAHPS submission requirements. We also refer hospitals and HCAHPS Survey vendors to the official HCAHPS website at: *http://www.hcahpsonline.org* for new information and program updates regarding the HCAHPS Survey, its administration, oversight, and data adjustments. We are not proposing any changes to these policies in this proposed rule.

i. Data Submission Requirements for Structural Measures

There are no remaining structural measures in the Hospital IQR Program.

j. Data Submission and Reporting Requirements for CDC NHSN HAI Measures

For details on the data submission and reporting requirements for Healthcare-Associated Infection (HAI) measures reported via the CDC's National Healthcare Safety Network (NHSN), we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51629 through 51633; 51644 through 51645), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50821 through 50822), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50259 through 50262). The data submission deadlines are posted on the QualityNet website.

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41547 through 41553), in which we finalized the removal of five of these measures (CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI) from the Hospital IQR Program. As a result, hospitals will not

be required to submit any data for those measures under the Hospital IQR Program following their removal beginning with the CY 2020 reporting period/FY 2022 payment determination. However, the five CDC NHSN HAI measures are included in the HAC Reduction and Hospital VBP Programs and reported via the CDC NHSN portal (83 FR 41474 through 41477; 83 FR 41449 through 41452). We further note that the HCP measure remains in the Hospital IQR Program and will continue to be reported via NHSN. We are not proposing any changes to these policies in this proposed rule.

10. Validation of Hospital IQR Program Data

a. Background

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539 through 53553), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50822 through 50835), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50262 through 50273), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49710 through 49712), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57173 through 57181), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38398 through 38403), and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41607 through 41608) for detailed information on validation processes for chart-abstracted measures and eCQMs, and previous updates to these processes for the Hospital IQR Program.

Validation for chart-abstracted measures has been updated over recent years as the number of chart-abstracted measures has been reduced. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41562 through 41567), we removed four clinical process of care measures,[472] and noted that for the CY 2021 reporting period/FY 2023 payment determination and subsequent years, only one clinical process of care measure (SEP–1) remains in the program for chart-abstracted validation (83 FR 41608).

We adopted the process for validating eCQM data in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57173 through 57181). Validation of eCQM data was finalized for the FY 2020 payment determination and subsequent years (starting with the validation of CY 2017 eCQM data that would impact FY 2020 payment determinations). We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38398 through 38403), in which we finalized several updates to the processes and procedures for validation of CY 2017 eCQM data for the FY 2020 payment determination, validation of CY 2018 eCQM data for the FY 2021 payment determination, and eCQM data validation for subsequent years.

In this proposed rule, we are proposing to incrementally combine the validation processes for chart-abstracted measure data and eCQM data and related policies in a stepwise process. To accomplish this, we are proposing to: (1) Update the quarters of data required for validation for both chart-abstracted measures and eCQMs; (2) expand targeting criteria to include hospital selection for eCQMs; (3) change the validation pool from 800 hospitals to 400 hospitals; (4) remove the current exclusions for eCQM validation selection, (5) require electronic file submissions for chart-abstracted measure data; (6) align the eCQM and chart-abstracted measure scoring processes; and (7) update the educational review process to address eCQM validation results. We believe these proposals will ultimately streamline the validation process and reduce the total number of hospitals selected for validation. These are discussed in detail in the following sections.

b. Submission Quarters

(1) Current Policy

Currently, we require hospitals selected for chart-abstracted measures to submit data from the Q3 and Q4 of the calendar year, 3 years before the payment determination and the Q1 and Q2 of the calendar year, 2 years before the payment determination (FY 2014 IPPS/LTCH final rule (78 FR 50822 through 50823). This is because there is a lag associated with validation. In general, validation is a year behind. Validation results affecting a certain FY payment determination are based on measures submitted for the prior payment determination. For example, validation results affecting the FY 2024 payment determination are based on measures submitted for the FY 2023 payment determination (CY 2021 discharge period with data submission completing in CY 2022).

For validation affecting the FY 2023 payment determination, hospitals must submit data to validate chart abstracted measures from the Q3 and Q4 of CY 2020 and the Q1 and Q2 of CY 2021. These are data originally submitted for the FY 2022 program payment determination. Depending on whether a hospital is selected as a random or targeted hospital, CMS requests data between 1 and 5 months following the data reporting submission deadline for a given reporting quarter. Following this request, hospitals have 30 days to submit randomly selected medical records to the Clinical Data Abstraction Center (CDAC), and after submission, CMS validates the data in preparation to make the associated payment determination. Under the current policy, hospitals selected for eCQM validation for a given payment determination year are required to provide medical records for a sample of cases occurring during one of the self-selected calendar quarters of the year 3 years before that payment determination (82 FR 38399 through 38400). For example, for validation affecting the FY 2023 payment determination period, hospitals selected during CY 2021 for eCQM validation are required to submit data from one self-selected quarter out of the 4 calendar quarters of 2020, that is Q1 through Q4 of CY 2020 (82 FR 38398 through 38403). These requirements are illustrated in the following table.

Current Quarters Required for Validation Affecting FY 2023 Payment Determination		
Measures Submitted	**Required Quarters of Data for Validation**	**Validation Data Request Timeframe**
Chart-Abstracted Measures	3Q 2020	4Q 2020 – 1Q 2021
	4Q 2020	1Q – 2Q 2021
	1Q 2021	2Q-3Q 2021
	2Q 2021	3Q -4Q 2021
eCQMs	1Q 2020 - 4Q 2020	2Q – 3Q 2021

[472] In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41562 through 41567), we removed three clinical process-of-care measures (IMM–2, ED–1, and VTE–6) for the CY 2019 reporting period/FY 2021 payment determination and subsequent years, and one clinical process of care measure (ED–2) for the CY 2020 reporting period/FY 2022 payment determination and subsequent years.

To support the transition to a combined validation process for both chart-abstracted measures and eCQMs, we are proposing to shift the quarters of data used for both chart-abstracted measure validation and eCQM validation in an incremental manner in order to align the two over time.

(2) Proposed Quarters Required for Validation Affecting the FY 2023 Payment Determination

In order to align the quarters used for chart-abstracted measure validation and eCQM validation, we are proposing to first change the period for validation affecting the FY 2023 payment determination. Instead of validating chart-abstracted measure data from Q3 2020–Q2 2021, we are proposing to validate measure data only from the Q3 and Q4 of CY 2020 for validation affecting the FY 2023 payment determination for chart-abstracted measures (illustrated in Table: 2 that follows) as a transition year. Specifically, this means that we would not require facilities to submit data for chart-abstracted measure validation for the Q1 and Q2 of CY 2021 for validation affecting the FY 2023 payment determination. We would use measure data from only two quarters (Q3 and Q4 of CY 2020) for hospitals selected under both the random and targeted chart-abstracted measure validations. We note that this proposal only affects chart-abstracted measure validation; we would continue to validate the self-selected quarter of eCQM data submitted during 2020 for validation affecting the FY 2023 payment determination as previously finalized.

Proposed Updates to Quarters Required for Validation Affecting the FY 2023 Payment Determination	
Measures Submitted	Required Quarters of Data for Validation
Chart-Abstracted Measures	3Q 2020
	4Q 2020
eCQMs	1Q 2020 - 4Q 2020

(3) Proposed Quarters Required for Validation Affecting the FY 2024 Payment Determination and Subsequent Years

For validation affecting the FY 2024 payment determination and subsequent years, we propose to use Q1–Q4 data of the applicable calendar year for validation of both chart-abstracted measures and eCQMs. For example, the quarters required for validation affecting the FY 2024 payment determination would occur as displayed in the following table.

Example: Proposed Quarter Alignment Used for Validation Affecting the FY 2024 Payment Determination	
Measures Submitted	**Required Quarters of Data for Validation**
Chart-Abstracted Measures	1Q 2021
	2Q 2021
	3Q 2021
	4Q 2021
eCQMs	1Q 2021 - 4Q 2021

We believe aligning the quarters of submission data used for both chart-abstracted measures and eCQM validation will allow hospitals selected for validation to more easily track and meet validation requirements, such as medical records requests from the CDAC.

We invite the public to comment on our proposal to incrementally align the quarters used for chart-abstracted measure and eCQM validation as previously discussed.

c. Proposed Combination of Chart-Abstracted Measure and eCQM Validation Beginning With Validation Affecting the FY 2024 Payment Determination

As noted previously, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57173), we finalized a separate validation process for eCQMs in the Hospital IQR Program. In addition to validating the chart-abstracted measures, we began validating an additional pool of up to 200 randomly selected hospitals for eCQMs (81 FR 57173).

Upon alignment of validation quarters as proposed in section VIII.A.10.b.(2). the preamble of this proposed rule, we wish to combine the validation process for both chart-abstracted measures and eCQMs. Therefore, in this proposed rule, we are proposing to remove the separate process for eCQM validation, beginning with the validation affecting the FY 2024 payment determination (for validation commencing in CY 2022 using data from the CY 2021 reporting period). Instead, beginning with validation affecting the FY 2024 payment determination and subsequent years, we are proposing to incorporate eCQMs into the existing validation process for chart-abstracted measures such that there would be one pool of hospitals selected through random selection and one pool of hospitals selected using targeting criteria, for both chart-abstracted measures and eCQMs. Under the aligned validation process, a single hospital would be selected for validation of both eCQMs and chart-abstracted measures and would be expected to submit data for both chart-abstracted measures and eCQMs. For specific data submission requirements, we refer readers to section VIII.A.10.e of the preamble of this proposed rule ''Number of Cases Required for Validation.''

(1) Targeted Selection of Hospitals for Validation

We refer readers to the FY 2013 IPPS/LTCH PPS Final Rule (77 FR 53552 through 53553) and the FY 2014 IPPS/LTCH PPS Final Rule (78 FR 50834) where we finalized targeted chart abstracted measure validation for a supplemental sample of hospitals in addition to random validation. The supplemental sample of hospitals includes all hospitals that failed validation in the previous year and a random sample of hospitals meeting certain targeting criteria. These criteria are as follows:

- Any hospital with abnormal or conflicting data patterns. One example of an abnormal data pattern would be if a hospital has extremely high or extremely low values for a particular measure. As described in the FY 2013 IPPS/LTCH PPS final rule, we define an extremely high or low value as one that falls more than 3 standard deviations from the mean which is consistent with the Hospital OQR Program (76 FR 74485). An example of a conflicting data pattern would be if two records were identified for the same patient episode of care but the data elements were mismatched for primary diagnosis. Primary diagnosis is just one of many fields that should remain constant across measure sets for an episode of care. Other examples of fields that should remain constant across measure sets are patient age and sex. Any hospital not included in the base validation annual sample and with statistically significantly more abnormal or conflicting data patterns per record than would be expected based on chance alone ($p < .05$), would be included in the population of hospitals targeted in the supplemental sample.
- Any hospital with rapidly changing data patterns. For this targeting criterion, we define a rapidly changing data pattern as a hospital which improves its quality for one or more measure sets by more than 2 standard deviations from 1 year to the next, and also has a statistically significant difference in improvement (one-tailed $p < .05$) (77 FR 53553).
- Any hospital that submits data to NHSN after the Hospital IQR Program data submission deadline has passed.
- Any hospital that joined the Hospital IQR Program within the previous 3 years, and which has not been previously validated.
- 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.
- Any hospital which failed to report to NHSN at least half of actual HAI events detected as determined during the previous year's validation effort.

In this proposed rule, we are proposing that beginning with validation affecting the FY 2024 payment determination, the existing targeting criteria would apply to all applicable hospitals, capturing both measure types (that is, chart-abstracted measures and eCQMs). In other words, we are proposing to expand targeted validation to include eCQMs, not just chart-abstracted measures. Doing so will facilitate the proposed combination of chart-abstracted and eCQM validation such that hospitals selected under this combined targeting approach would be validated for both chart-abstracted and eCQMs.

Additionally, we are clarifying that a hospital that has been granted an Extraordinary Circumstances Exception could still be selected for validation (chart-abstracted measures and eCQMs) under the targeting criteria. We invite public comment on our proposal.

(2) Number of Hospitals

In the FYs 2013 and 2014 IPPS/LTCH PPS final rules (77 FR 53551 through 53554, 78 FR 50833), we finalized that for chart-abstracted measure validation, we take an annual sample from 400 randomly selected hospitals and from up to 200 hospitals selected using targeting criteria. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57173 through 57178), we finalized that for eCQMs, we take an annual sample of up to 200 randomly selected hospitals that have not been selected for chart-abstracted measure validation. Under these existing policies, we may validate data from up to a total of 800 hospitals for a given year for both chart-abstracted measures and eCQMs.

In this proposed rule, we are proposing to change the hospital selection policies to reduce the total number of hospitals selected for validation from up to 800 hospitals to up to 400 hospitals, beginning with validation affecting the FY 2024 payment determination. We are proposing that up to 200 hospitals would be selected randomly and up to 200 would be selected using targeted criteria. Detailed descriptions on proposals to effectuate that reduction follow.

(a) Proposed Number of Hospitals Under Random Selection

Instead of taking an annual sample from 400 randomly selected hospitals as previously finalized, we are proposing to reduce the number of hospitals selected at random for validation to up to 200 hospitals, beginning with validation affecting the FY 2024 payment determination (measure data collected during CY 2021 and submitted during CY 2022 for the FY 2023 payment determination). We are proposing these changes in conjunction with the HAC Reduction Program and refer readers to section IV.M. of this proposed rule for those proposals. We believe that reducing the total number of hospitals selected for chart-abstracted measure validation each year to ''up to 200'' would maintain a sufficient sample size for a statistically meaningful estimate of hospitals' reporting accuracy and help streamline the process for both programs.

One of our goals for the annual random sample is to estimate the total percentage of hospitals in the Hospital IQR Program that have been reporting unreliable data. The basic premise behind random sampling is that one can learn something about all hospitals by gathering data on just a subset of hospitals (77 FR 53552). The minimum sample size required to assess the percentage of hospitals in the Hospital IQR Program that have been reporting unreliable data depends on the expected percentage of hospitals that fail validation. Because a very high percentage of Hospital IQR Program hospitals pass validation (96.4 percent for the FY 2018 payment determination, 95.8 percent for the FY 2019 payment determination, and 96.2 percent for the FY 2020 payment determination), we believe that we can reduce burden on hospitals by selecting fewer hospitals for the base annual random sample without adversely affecting our estimate of this percentage. Using an estimated passing rate of 96 percent, our power calculations indicate that with a pool of up to 200 hospitals, we can be highly confident that at least 94.8 percent of all hospitals in the Hospital IQR Program population are achieving the requisite reliability score.

In addition, in the FY 2019 IPPS/LTCH PPS final rule, we finalized removal of five healthcare associated infection measures [473] from the Hospital IQR Program and incorporated the same measures into the HAC Reduction Program (83 FR 41547 through 41553). Because of this, in the FY 2019 IPPS/LTCH PPS final rule, we also created validation policies under the HAC Reduction Program (83 FR 41479 through 41483). Following the transfer

[473] CAUTI, CDI, CLABSI, Colon and Abdominal Hysterectomy SSI, and MRSA Bacteremia.

of NHSN HAI measure validation to the HAC Reduction Program, in this proposed rule, we are proposing that both the Hospital IQR Program and the HAC Reduction Program use a single random hospital sample of up to 200 hospitals beginning with validation affecting the FY 2024 payment determination. In other words, hospitals would be randomly selected and this pool of up to 200 hospitals would be validated under both programs.

We are proposing to change the Hospital IQR Program policy from an exact number of hospitals selected for random validation (that is, 400) to a range (that is, up to 200). This is because there are some hospitals that are eligible for the HAC Reduction Program, but which do not also participate in the Hospital IQR Program. Over 95 percent of hospitals that are eligible for the HAC Reduction Program also participate in the Hospital IQR Program. The small proportion of hospitals that do not participate in the Hospital IQR Program would be included in the single pool from which hospitals could be randomly selected; however, if such a hospital were selected for validation, it would not be required to submit data for validation under the Hospital IQR Program. Therefore, selecting a single sample for both programs could potentially result in a number totaling less than 200 hospitals for validation of Hospital IQR Program chart-abstracted data because hospitals that are eligible for the HAC Reduction Program, but do not participate in the Hospital IQR Program would not be validated in the Hospital IQR Program. This is consistent with the previously finalized Hospital IQR Program chart-abstracted validation process, for which hospitals were subject to both chart-abstracted measure validation as well as HAI measure validation (83 FR 41608). The only difference is that HAI measure validation has since moved to the HAC Reduction Program and, hence, the HAI validation performance will be accounted for under the HAC Reduction Program.

We believe that this proposed approach would simplify validation for hospitals under both programs. This proposal enables us to continue validating Hospital IQR Program chart-abstracted data without increasing the total number of hospitals selected for validation across both programs. We also refer readers to section IV.M. of the preamble of this proposed rule for more detail on the validation proposals for the HAC Reduction Program. Again, we note that this proposal is being made in conjunction with that in the HAC Reduction Program, and finalization of this proposal in the Hospital IQR Program would be contingent on the HAC Reduction Program proposal also being finalized.

We invite public comment on this proposal.

(B) Exclusion Criteria

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38399), we finalized exclusion criteria, applied before the random selection of up to 200 hospitals for eCQM validation. The exclusion criteria include any hospital—

- Selected for chart-abstracted measure validation;
- That has been granted an Extraordinary Circumstances Exception (ECE); and
- That does not have at least five discharges for at least one reported eCQM included among their QRDA I file submissions. (81 FR 57174, 82 FR 38399). Hospitals meeting one or more of these exclusion criteria are not eligible for selection for eCQM validation each year (82 FR 38399).

In this proposed rule, in conjunction with our proposal to combine chart-abstracted measure and eCQM validation, we are proposing to remove all of the previously finalized exclusion criteria (as previously referenced) beginning with validation affecting the FY 2024 payment determination and for subsequent years. Since a separate sample of hospitals for eCQM validation will no longer need to be identified, the previously finalized exclusion criteria for eCQM validation hospital selection will no longer be needed. We invite public comment on our proposal to remove the previously finalized exclusion criteria. Finalization of this proposal would be contingent on finalization of our proposal to combine chart-abstracted measure and eCQM validation.

(c) Number of Hospitals Selected Under Targeted Selection

We refer readers to FY 2013 IPPS/LTCH PPS final rule (77 FR 53552 through 53553) where we previously established that we would select up to 200 hospitals for chart abstracted measures data validation using the targeting criteria described in section VIII.A.11.c. of the preamble of this proposed rule. The Hospital IQR Program does not currently have a policy for targeted selection of hospitals for eCQM validation.

In this proposed rule, while we are not proposing any changes to the number of hospitals selected using targeting criteria, in sections VIII.A.3.c.(1) and VIII.A.10.a of this proposed rule, we are proposing to combine chart-abstracted measure and eCQM validation and to decrease the number of randomly selected hospitals. If these proposals are both finalized, the total number of hospitals selected for validation (for both chart abstracted measures and eCQMs) would be at maximum 400 (up to 200 hospitals randomly selected + up to 200 hospitals using targeting criteria). The current and proposed validation hospital numbers and measure types are illustrated in the tables that follow:

Current Validation Process		
Selection Process	**Number of Hospitals**	**Measure Type**
Random Selection	400	Chart-Abstracted
Targeted Selection	Up to 200	Chart-Abstracted
Random Selection	Up to 200	eCQMs
Total:	Up to 800	

Proposed Validation Process Beginning with Validation Affecting the FY 2024 Payment Determination		
Selection Process	Number of Hospitals	Measure Type
Random Selection	Up to 200	Chart-Abstracted and eCQM
Targeted Selection	Up to 200	Chart-Abstracted and eCQM
Total:	Up to 400	Chart-Abstracted and eCQM

Under the proposed aligned validation process, the Hospital IQR Program would validate a pool of up to 400 hospitals (up to 200 randomly selected and up to 200 selected using the targeting criteria), across both measure types.

d. Proposed Use of Electronic File Submissions for Chart-Abstracted Measure Medical Records Requests Beginning With Validation Affecting the FY 2024 Payment Determination

Currently, hospitals may choose to submit paper copies of medical records for chart-abstracted measure validation (75 FR 50226), or they may submit copies of medical records for validation by securely transmitting electronic versions of medical information (78 FR 50834, 79 FR 50269). Submission of electronic versions can either entail downloading or copying the digital image of the medical record onto CD, DVD, or flash drive (78 FR 50835), or submission of PDFs using a secure file transmission process after logging into the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System) (79 FR 50269). We reimburse hospitals at $3.00 per chart (78 FR 50956). Neither paper copies nor submission of CD, DVD, or flash drive is applicable for eCQMs since that data is required to be submitted electronically via Secure File Transfer (81 FR 57174 through 57178).

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 FY 2024 payment determination (*i.e.,* beginning with data submission for Q1 of CY 2021). 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 FY 2024 payment determination (*i.e.,* Q1 of CY 2021) 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. We would continue to reimburse hospitals at $3.00 per chart, consistent with the current reimbursement amount for electronic submissions of charts.

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 (78 FR 50834). 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. 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.

e. Number of Cases Required for Validation

(1) Chart-Abstracted Measures

We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57179 through 57180) where we established a process in which the CDAC contractor requests selected hospitals to submit eight randomly selected medical records on a quarterly basis from which data are abstracted (for a total of 32 records per year). Once the CDAC contractor receives the data, it re-abstracts the measures which were submitted by the hospitals for the Hospital IQR Program and calculates the percentage of matching measure numerators and denominators for each measure within each chart submitted by the hospital. Each selected case may have multiple measures included in the validation. We are not proposing any changes to the number of cases required from each selected hospital for chart-abstracted measure validation.

(2) eCQMs

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38398 through 38399), we finalized that selected hospitals must submit eight cases per reported quarter to complete eCQM data validation. We consider a sample of eight cases per quarter to be the minimum sample size needed to accurately ascertain the quality of the reported data (82 FR 38399). Each selected case may have multiple measures included in the validation.

In this proposed rule, we are not proposing any changes to this policy. However, we refer readers to section VIII.A.10.e of the preamble (Reporting and Submission Requirements for eCQMs) of this proposed rule for more details on our proposal to increase the

number of quarters for which hospitals are required to report eCQM data: From one self-selected quarter of data to four quarters of data progressively over several years. If those proposals are finalized, hospitals selected for validation would be required to submit: (1) A total of 16 requested cases from 2 calendar quarters of data (8 cases × 2 quarters) for validation affecting the FY 2024 payment determination; (2) a total of 24 requested cases from 3 quarters of data (8 cases × 3 quarters) for validation affecting the FY 2025 payment determination; and (3) a total of 32 requested cases over 4 quarters of data (8 cases × 4 quarters) for validation affecting the FY 2026 payment determination and for subsequent years. This means that for eCQM validation, hospitals will have to submit validation data for each quarter of their self-selected eCQM submission quarters.

f. Scoring Processes

(1) Current Scoring Process

Currently, there are two separate processes for payment determinations related to validation requirements—one for chart-abstracted measure validation and another for eCQM validation.

For chart-abstracted measure validation scoring, under the current process, the CDAC contractor requests that hospitals submit eight randomly selected medical records on a quarterly basis from which data are abstracted and submitted by the hospital to the Clinical Data Warehouse (for a total of 32 records per year per hospital). Once the CDAC contractor receives the data, it re-abstracts the same data submitted by the hospitals and calculates the percentage of matching measure numerators and denominators for each measure within each chart submitted by the hospital (81 FR 57179 through 57180). Each selected case may have multiple measures included in the validation score. Specifically, one patient may meet the numerator and denominator criteria for multiple measures, and therefore, would generate multiple measures in the validation score. Consistent with previous years, each quarter and clinical topic is treated as a stratum for variance estimation purposes. Approximately 4 months after each quarter's validation submission deadline, validation results for chart-abstracted measures for the quarter are posted on the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System). At the end of the year, the validation score is calculated by combining the data from all four quarters into one agreement rate for each hospital. At this point, CMS calculates a confidence interval around the agreement rate for each hospital using a normal distribution assumption. The upper bound of the confidence interval is calculated as the final validation score. A hospital must attain at least a 75 percent validation score based upon all four quarters of chart-abstracted data validation to pass the validation requirement. The overall validation score from the chart-abstracted measure is used to determine whether a hospital has met the validation requirement under the Hospital IQR Program for purposes of the annual payment update. Specifically, if a hospital fails chart-abstracted validation (because the validation score was below 75 percent), it would receive an applicable annual reduction to the hospital's IPPS market basket update (APU) for failing to meeting all Hospital IQR Program requirements.

eCQM validation is different, because the accuracy of eCQM data submitted for validation (as measured by the agreement rate) does not currently affect a hospital's payment determination as described in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57181). As finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38398 through 38399), selected hospitals must submit eight cases, per self-selected quarter to complete eCQM data validation. Because the reporting quarter is self-selected, validation occurs on an annual basis using all 8 cases that are submitted. For hospitals to receive their full APU, they must provide 75 percent of requested eCQM medical records in a timely and complete manner (82 FR 38398 through 82 FR 38401). Hospitals receive eCQM validation results through email communications on an annual basis.[474]

(2) Proposed Weighted Scoring

To support the transition to a combined validation process for both chart-abstracted measures and eCQMs, we are proposing to provide one combined validation score starting with validation affecting the FY 2024 payment determination and for subsequent years. Specifically, this single score would reflect a weighted combination of a hospital's validation performance for chart-abstracted measures and eCQMs. Since eCQMs are not currently validated for accuracy, we propose that the eCQM portion of the combined agreement rate would be multiplied by a weight of zero percent and chart abstracted measure agreement rate would be weighted at 100 percent for validation affecting the FY 2024 payment determination and subsequent years (*i.e.,* starting with the CY 2021 discharge data submitted for FY 2023 payment determination and validation affecting the FY 2024 payment determination). The agreement rate and associated confidence interval would be calculated based on the validation data collected from each hospital for each fiscal year. The validation score associated with the combined agreement rate would be the upper bound of the calculated confidence interval. For more detailed information on the confidence interval, please refer to the Chart-Abstracted Data validation page of QualityNet: *https://www.qualitynet.org/inpatient/data-management/chart-abstracted-data-validation*. Under this proposal however, in the absence of an eCQM score that reflects reporting accuracy, hospitals would continue to be required to successfully submit at least 75 percent of the requested medical records for eCQM validation. Submission of requested medical records at or in excess of this threshold would meet the eCQM validation requirements. Under this proposal, hospitals would continue to receive their total validation score annually.

As we move forward, we will determine when eCQM measure data are ready for accuracy scoring for validation. In this proposed rule, we are proposing to progressively increase the number of eCQM validation cases (from 8 cases for validation affecting FY 2023 payment determination, to 16 cases for validation affecting FY 2024 payment determination, to 24 cases for validation affecting FY 2025 payment determination, and to 32 cases for validation affecting FY 2026 payment determination and beyond). The additional cases collected and validated under the proposal will support the calculation of a statistically robust validation score. We anticipate increasing the eCQM validation score weighting in the future to include eCQM measures accuracy as part of the overall validation score. Any adjustments in the weighting and scoring would be proposed through future rulemaking. We invite public comments on our proposal.

g. Summary

Our validation proposals are summarized in the following table:

[474] *https://qualitynet.org/inpatient/data-management/ecqm-data-validation.*

	Quarters of Data Required for Validation	Scoring
Proposed Process for Validation Affecting the FY 2023 Payment Determination		
Chart-Abstracted Measures Validation: 400 Random Hospitals + up to 200 Targeted Hospitals	3Q 2020	At least 75% validation score
	4Q 2020	
eCQM Validation: Up to 200 Random Hospitals	1Q 2020 - 4Q 2020	Successful submission of at least 75% of requested medical records
Proposed Process for Validation Affecting the FY 2024 Payment Determination and Subsequent Years		
COMBINED Process (Chart-Abstracted Measures and eCQM Validation): up to 200 Random Hospitals + up to 200 Targeted Hospitals	1Q 2021 - 4Q 2021	Chart-abstracted Measures: At least 75% validation score (weighted at 100%) And eCQMs: Successful submission of at least 75% of requested medical records

h. Educational Review Process

(1) Chart-Abstracted Measures

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50260), we established an educational review process for validation of chart-abstracted measures. The process was subsequently updated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38402 through 38403). In this process, hospitals may request an educational review if they believe they have been scored incorrectly or if they have questions about their validation results. As noted above, approximately 4 months after each quarter's validation submission deadline, validation results for chart-abstracted measures for the quarter are posted on the QualityNet Secure Portal (also referred to as the Hospital Quality Reporting (HQR) System). Hospitals have 30 calendar days following the date validation results are posted to identify any potential CDAC or CMS errors for the first three quarters of validation results and contact the Validation Support Contractor (VSC) to request an educational review. Upon receipt of an educational review request, we review the data elements identified in the request, as well as the written justifications provided by the hospital. We provide the results of an educational review, outlining the findings of whether the scores were correct or incorrect, to the requesting hospital through a CMS-approved secure file transmission process (82 FR 38402). We note that at the end of the year, the validation score is calculated by combining the data from all four quarters into one agreement rate for each hospital.

If an educational review yields incorrect CMS validation results for chart-abstracted measures, we use the corrected quarterly score, as recalculated during the educational review process to compute the final confidence interval (82 FR 38402). We use the revised score identified through an educational review when determining whether or not a hospital failed validation (82 FR 38402). Corrected scores, however, are only used if they indicate that the hospital performed more favorably than previously determined (82 FR 38402).[475] We note that corrections only occur to calculations, not to the underlying measure data (82 FR 38402). A detailed description of the educational review process for validation of chart-abstracted measures is also available on the QualityNet website. We are not proposing any changes to our educational review process for chart-abstracted measures.

(2) Proposed Educational Review Process for eCQMs for Validation Affecting the FY 2023 Payment Determination and Subsequent Years

In this proposed rule, we are proposing to extend a similar process established for chart-abstracted measure validation educational reviews to eCQM validation beginning with validation affecting the FY 2023 payment determination and subsequent years (that is, starting with data from CY 2020). While we are proposing to combine the hospital pool and generate a single score for both eCQM and chart-abstracted measure data validation, these underlying processes would still remain distinct because the underlying data being validated is distinct. We believe that expanding the educational review process to incorporate eCQMs would allow hospitals to better understand the processes and data for eCQM validation. Under our proposal, hospitals may request an educational review if they believe they have been scored incorrectly or if they have questions about their validation of eCQMs. Specifically, a hospital would have 30 calendar days to contact the VSC to solicit a written explanation of the validation performance following the date that the validation results were provided to the hospital. Because hospitals receive eCQM validation results on an annual basis, however, they would have the opportunity to request an educational review once annually following receipt of their results. Upon receipt of an educational review request, we would review the requested data elements and written justifications provided by the hospital. We are also proposing to provide the results of the eCQM validation educational review to the requesting hospital, outlining the findings of whether the scores were correct or incorrect, through a CMS-approved secure file transmission process.

We invite public comment on our proposal.

11. Data Accuracy and Completeness Acknowledgement (DACA) Requirements

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554) for previously adopted details on DACA requirements. We are not proposing any changes to this policy in this proposed rule.

12. Public Display Requirements

a. Background

Section 1886(b)(3)(B)(viii)(VII) of the Act requires the Secretary to report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate

[475] Hospitals may still request reconsideration even if an educational review determined that a hospital was scored correctly. Hospitals that fail Hospital IQR Program requirements, including validation, may request reconsideration after receiving notification of their payment determination for the applicable fiscal year.

to services furnished in inpatient settings in hospitals on the internet website of CMS. Section 1886(b)(3)(B)(viii)(VII) of the Act also requires that the Secretary establish procedures for making information regarding measures available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. Our current policy is to report data from the Hospital IQR Program as soon as it is feasible on CMS websites such as the *Hospital Compare* and/or its successor website after a 30-day preview period (78 FR 50776 through 50778). We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47364), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49712 through 49713), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409), and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41539) for details on public display requirements. The Hospital IQR Program quality measures are typically reported on the *Hospital Compare* website at: *http://www.medicare.gov/hospitalcompare*, or its successor website, and on occasion are reported on other CMS websites such as: *https://data.medicare.gov*, or its successor website.

b. Proposed Public Reporting of eCQM Data

(1) Background

The Hospital IQR Program initiated voluntary reporting of eCQM data in the FY 2014 IPPS/LTCH PPS final rule, for the CY 2014 reporting period/FY 2016 payment determination (78 FR 50807 through 50810). At that time, we noted our belief that electronic collection and reporting of quality data using health IT would ultimately simplify and streamline quality reporting (78 FR 50807). Based on our ongoing experience with eCQMs, we continue to believe this. We also believe that electronic reporting furthers CMS and HHS policy goals to promote quality through performance measurement and, in the long-term, will both improve the accuracy of the data and reduce reporting burden for providers. We expect that over time, hospitals will continue to leverage EHRs to capture, calculate, and electronically submit quality data, build and refine their EHR systems, and gain more familiarity with reporting eCQM data (78 FR 50807).

Since the FY 2014 IPPS/LTCH PPS final rule, the Hospital IQR Program's eCQM reporting requirements have evolved. In the FY 2016 IPPS/LTCH PPS final rule, the reporting of eCQM data became required (rather than voluntary) under the Hospital IQR Program, beginning with the CY 2016 reporting period/FY 2018 payment determination (80 FR 49693 through 49698). At the time of publication of this proposed rule, hospitals will have completed the reporting of eCQM data for the CY 2019 reporting period/FY 2021 payment determination by the March 2, 2020 submission deadline, the fourth year of required eCQM reporting.

Most recently, in the FY 2020 IPPS/PPS LTCH final rule, we finalized the Hospital IQR Program's reporting requirements for the CY 2022 reporting period/FY 2024 payment determination, to require that hospitals report one self-selected calendar quarter of data for: (a) Three self-selected eCQMs; and (b) the Safe Use of Opioids—Concurrent Prescribing eCQM (Safe Use eCQM), for a total of four eCQMs (84 FR 42503). We refer readers to section VIII.A.10.e of the preamble of this proposed rule where we discuss our proposal to progressively increase the quarters of eCQM data, beginning with the CY 2022 reporting period/FY 2024 payment determination.

As eCQM reporting for the Hospital IQR Program continues to advance and hospitals have gained several years of experience with successfully collecting and reporting eCQM data, we believe it is important to further our policy goals of leveraging EHR-based quality measure reporting in order to incentivize data accuracy, promote interoperability, increase transparency, and reduce long-term provider burden by providing public access to the reported eCQM data. Originally, as we incorporated eCQMs into the Hospital IQR Program on a voluntary basis, we stated that we would need time to assess the data submitted by hospitals to determine the optimal timing and transition strategy for publicly reporting eCQM data (78 FR 50813). We finalized that eCQM data reported for the Hospital IQR Program would only be publicly reported if we determine the data are accurate enough to be reported (78 FR 50818). In the FY 2016 IPPS/LTCH PPS final rule when we made the reporting of eCQMs required rather than voluntary, we stated that any data submitted electronically would not be posted on the *Hospital Compare* website at that time, and that we would address public reporting in future rulemaking, after the conclusion and assessment of the validation pilot (80 FR 49698).

The eCQM validation pilot was completed in 2015 and was addressed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57173 through 57174). Building upon the validation pilot, we adopted procedures to begin the required validation of eCQM data under the Hospital IQR Program in the FY 2017 IPPS/LTCH PPS final rule, and stated that the first validation of eCQM data would occur in spring 2018 to validate data from the CY 2017 reporting period. As finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57180 through 57181), the validation process for eCQMs was established as an incremental process to ensure hospitals are able to successfully report the medical records that correspond to the data used for eCQM measure reporting. eCQM validation scoring is different, because the accuracy of eCQM data submitted for validation currently does not currently affect a hospital's payment determination. The eCQM validation process was established as an incremental process to ensure hospitals are able to successfully report the medical records that correspond to the data used for eCQM measure reporting.

Our validation of eCQM data submitted from CY 2017 and CY 2018 has demonstrated that hospitals are capable of reporting eCQM measure data. Since the eCQM validation pilot, we have completed eCQM data validation from the CY 2017 reporting period and the CY 2018 reporting period, and worked with stakeholders to develop a more fulsome understanding of the eCQM data submitted. Our review of the CY 2017 and CY 2018 eCQM data submitted for validation included an analysis of over 1,200 patient episodes of care submitted by over 190 hospitals per reporting period. The majority of hospitals successfully submitted validation records within the timeline requested. The results demonstrate that hospitals report the majority of eCQM data with agreement rates of 80 percent or better. Agreement rates are the ratios which reflect the frequency at which a hospital's electronically reported medical record data matches results adjudicated by the Clinical Data Abstraction Center (CDAC). CMS calculates an agreement rate for each hospital. Our analysis demonstrates that hospitals continue to improve the accuracy of identifying patients appropriate for measure denominator inclusion, and tend to accurately report a wide variety of data types, including diagnoses, medications, and laboratory values. [Based on our review of the CY 2017 and CY 2018 eCQM data submitted

for validation, and on the finding that the majority of eCQM data was reported with agreement rates of 80 percent or better, we believe eCQM data are accurate enough to be publically reported in aggregate. Because eCQM validation examines eCQMs on a chart-by-chart basis (as opposed to in aggregate) and affects payment, in section VIII.A.10.f. above, we propose that eCQM validation continue to be based on successful submission of at least 75 percent of the requested medical records for eCQM validation instead of reporting accuracy. In the interests of providing data to the public as quickly as possible, and as expressed in more detail below, we are proposing to begin public reporting of eCQM data.

(2) Proposal To Begin Publicly Reporting eCQM Data Beginning With the eCQM Data Reported by Hospitals for the CY 2021 Reporting Period/FY 2023 Payment Determination

Based on our validation of eCQM data submitted from CY 2017 and CY 2018, and in alignment with our goal to encourage data accuracy and transparency, in this proposed rule, we are proposing to begin publicly reporting eCQM data beginning with the eCQM data reported by hospitals for the CY 2021 reporting period/FY 2023 payment determination and for subsequent years. These data could be made available to the public as early as the fall of 2022. We refer readers to section VIII.A.10.f.(2) of the preamble to this proposed rule for a discussion of proposed chart-abstracted measure and eCQM validation weighted scoring.

As with other Hospital IQR Program measures, hospitals would have the opportunity to review their data before they are made public, as required by section 1886(b)(3)(B)(viii)(VII) of the Act, during a 30-day preview period in accordance with previously finalized policies (76 FR 51608). Measure data, including eCQM data, are published on the *Hospital Compare* and/or *https://data.medicare.gov* websites or successor websites.

We plan to continue assessing the eCQM data submitted in future years and will continue working to ensure that hospitals receive feedback on their validation results aimed at improving transparency and reporting accuracy. We are committed to providing data to patients, consumers, and providers as quickly as possible so they are empowered to make informed decisions about their own, and their patients' healthcare.

Understanding that it will be important for hospitals and stakeholders alike to know how to find the eCQM data once they are publicly posted, we would convey any updates to the posting locations through routine communication channels to hospitals, vendors, and QIOs, including, but not limited to, issuing memos, emails, and notices on the QualityNet and eCQI Resource Center websites.

We also refer readers to section VIII.D. of the preamble of this proposed rule for a similar proposal in the Medicare Promoting Interoperability Program. We are soliciting public comment on this proposal.

13. Reconsideration and Appeal Procedures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650 through 51651), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), and 42 CFR 412.140(e) for details on reconsideration and appeal procedures for the FY 2017 payment determination and subsequent years. We are not proposing any changes to this policy in this proposed rule.

14. Hospital IQR Program Extraordinary Circumstances Exceptions (ECE) Policy

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651 through 51652), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836 through 50837), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57181 through 57182), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38409 through 38411), and 42 CFR 412.140(c)(2) for details on the current Hospital IQR Program ECE policy. We also refer readers to the QualityNet website at: *http://www.QualityNet.org/* for our current requirements for submission of a request for an exception. We are not proposing any changes to this policy in this proposed rule.

B. Proposed Changes to the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

1. Background

The PPS-Exempt-Cancer Hospital Quality Reporting (PCHQR) Program is authorized by section 1866(k) of the Act, and it applies to hospitals described in section 1866(d)(1)(B)(v) (referred to as ''PPS-Exempt Cancer Hospitals'' or ''PCHs''). Under the PCHQR Program, PCHs must submit to the Secretary data on quality measures with respect to a program year in a form and manner, and at a time, specified by the Secretary.

For additional background information, including previously finalized measures and other policies for the PCHQR Program, we refer readers to the following final rules: The FY 2013 IPPS/LTCH PPS final rule (77 FR 53556 through 53561); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50838 through 50846); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277 through 50288); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713 through 49723); the FY 2017 IPPS/LTCH PPS final rule (81 FR 57182 through 57193); the FY 2018 IPPS/LTCH PPS final rule (82 FR 38411 through 38425); the FY 2019 IPPS/LTCH PPS final rule (83 FR 41609 through 41624); CY 2019 OPPS/ASC final rule with comment period (83 FR 59149 through 59154); and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42509 through 42524).

In this proposed rule, we are proposing to incorporate refinements to two existing measures in the PCHQR Program measure set—the Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138) and the Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139). While we are not proposing to add any new measures or remove any existing measures, we continue to assess the PCHQR Program measure set's alignment with the Meaningful Measures Initiative, which is discussed in more detail in I.A.2. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41147 through 41148).

2. Summary of PCHQR Program Measures for the FY 2023 Program Year

The table in this section of this rule summarizes the PCHQR Program measure set for the FY 2023 program year.

FY 2023 PCHQR Program Measure Set

Short Name	NQF Number	Measure Name
Safety and Healthcare-Associated Infection (HAI) Measures		
CAUTI	0138	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure
CLABSI	0139	National Healthcare Safety Network (NHSN) Central line-associated Bloodstream Infection (CLABSI) Outcome Measure
HCP	0431	Influenza Vaccination Coverage Among Healthcare Personnel
Colon and Abdominal Hysterectomy SSI	0753	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery]
MRSA	1716	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure
CDI	1717	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure
Clinical Process/Oncology Care Measures		
EOL-Chemo	0210	Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life
EOL-Hospice	0215	Proportion of Patients Who Died from Cancer Not Admitted to Hospice
N/A	0383	Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology
Intermediate Clinical Outcome Measures		
EOL-ICU	0213	Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life
EOL-3DH	0216	Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days
Patient Engagement/Experience of Care Measure		
HCAHPS*	0166	HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) Survey
Claims Based Outcome Measures		
N/A	N/A	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
N/A	3188	30-Day Unplanned Readmissions for Cancer Patients
N/A	N/A	Surgical Treatment Complications for Localized Prostate Cancer

***Note:** In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42509 through 42524), we finalized our proposal to remove the "pain management questions" from the HCAHPS survey beginning with October 2019 discharges.

3. Proposed Refinements to the Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138) and the Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139) Beginning With the FY 2023 Program Year

a. Background

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53556 through 53559), we adopted the Catheter-associated Urinary Tract Infection (CAUTI) (NQF #0138) and Central line-associated Bloodstream Infection (CLABSI) (NQF #0139) measures for use in the PCHQR Program beginning with the FY 2014 program year, and we refer readers to this rule for a detailed discussion of these measures. In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20503), we proposed to remove both measures from the program because we believed that removing the measures would reduce program costs and complexities associated with the use of these data by patients in decision-making. We stated that we believed the costs, coupled with the high technical and administrative burden on PCHs associated with collecting and reporting the measure data, outweighed the benefits of their continued use. We further stated that it had become difficult for CMS to publicly report data on these measures due to the low volume of data produced and reported by the small number of PCHs that participate in the PCHQR

Program, and that we lacked an appropriate methodology to publicly report these data. For these reasons, we believed that the measures should be removed beginning with the FY 2021 program year under measure removal Factor 8: The costs associated with the measures outweighed the benefit of their continued use in the program.

However, after considering the comments we had received on this proposal and other updated information, in the CY 2019 OPPS/ASC final rule (83 FR 59150), we decided to retain both the CAUTI and CLABSI measures in the PCHQR Program. We stated that since the time we made our proposal, we had conducted our own analyses regarding the continued use of the CAUTI and CLABSI measures using updated CDC data. We also stated that although the CDC had previously believed that oncology unit locations, including those in PCHs, had a higher incidence of infections than other types of units in acute care hospitals, the CDC now believes, after controlling for location type, that oncology unit locations in PCHs do not have a higher incidence of infection than oncology units within other acute care hospitals. We stated that the CDC's updated analysis also produced a consistent finding that cancer hospital status was not a significant risk factor in any of the device-associated HAI risk models, including those used for CAUTI and CLABSI. Lastly, we stated that we believe these results indicate that reporting PCH CAUTI and CLABSI performance measure data is just as important as reporting acute care hospital CAUTI and CLABSI performance measure data (83 FR 59151). Based on this updated information, as well as the public comments, we concluded that the importance of emphasizing patient safety in quality care delivery justified retaining the CAUTI and CLABSI measures in the PCHQR Program (83 FR 59151).

We also noted in the CY 2019 OPPS/ASC PPS final rule that the CAUTI and CLABSI measure specifications had been recently updated to use new standard infection ratio (SIR) calculations that can be applied to cancer hospitals, including PCHs. We noted that this updated SIR calculation methodology is different than the methodology we are currently using to calculate the CAUTI and CLABSI measures. Additionally, the use of raw location-stratified rates in the current methodology had created a concern that the CAUTI and CLABSI data calculated under the current methodology might appear to inaccurately show lower performance among PCHs than the performance reported by acute care hospitals that are reporting CAUTI and CLABSI data using the updated methodology (83 FR 59151). We stated that we believed the updated methodology addresses this concern because the updates include rates that are stratified by patient care locations within PCHs, without the use of predictive models or comparisons in the rate calculations. We also stated that we intended to propose to adopt these updated versions of the CAUTI and CLABSI measures, and that we would work closely with the CDC to assess the updated risk adjusted versions of these measures (83 FR 59151).

b. Proposed Updates to the CAUTI and CLABSI Measures

In this proposed rule, we are proposing to refine the CAUTI and CLABSI measures by adopting the updated SIR calculation methodology developed by the CDC that calculates rates that are stratified by patient care locations within PCHs, without the use of predictive models or comparisons in the rate calculations.

(1) Description of the CDC Re-Baselining Efforts

The CDC's National Healthcare Safety Network (NHSN) uses healthcare-associated infection (HAI) incidence data from a prior time period and a standard population of facilities that report data to the NHSN (such as all healthcare facilities of a specified type) to establish a HAI baseline for those facilities, including a HAI baseline for CAUTI and CLABSI.[476] The NHSN then uses that baseline to calculate the SIR. For both of these measures, the SIR is calculated as a comparison of the actual number of HAIs reported by a facility with the number that would be predicted by the HAI baseline.[477]

In 2016, the CDC used 2015 HAI incidence data to update both the source of aggregate data and the risk adjustment methodology used to create the HAI baselines. As a result, the CDC established new HAI baselines for purposes of calculating the SIRs used to calculate HAI measures, including the CAUTI and CLABSI measures.[478] The CDC's decision to use 2015 data was multifactorial and relied partially on its implementation of updated surveillance protocols and definitions as well as increased reporting of certain HAI types by additional healthcare facility types.[479]

During its re-baselining effort, the CDC determined that it could generate HAI baselines that produce more accurate SIR calculations for the 17 hospitals that enroll in NHSN as facility type ''HOSP–ONC'' (11 PCHs and 6 other hospitals that classify themselves as cancer hospitals but are not PCHs for purposes of Medicare) by standardizing the new HAI baselines across infection type and facility type.[480] Therefore, the CDC created a risk adjustment model for acute care hospitals and determined that it could include the 17 cancer hospitals that in that risk adjustment model because it found that cancer hospital status was not a significant risk factor that would preclude their inclusion.[481]

The CDC also evaluated what additional oncology-specific patient locations (for example, hematology/oncology ward, medical oncology ICU) should be adjusted for when deriving SIR calculations for hospitals in the acute care risk adjustment model. The CDC considered this because examining patient care location allows for the assessment of which patient populations are at higher risk for CAUTI and CLABSI incidences. Further, stakeholders had previously raised concerns that the omission of a risk adjustment for oncology-specific patient care locations in the SIR calculations could inaccurately appear to show lower performance on the HAI measures, including CLABSI and CAUTI, by PCHs and other cancer hospitals than other acute care hospitals; adjusting for oncology-specific patient locations as a part of the new risk model mitigates this concern. When the CDC stratified by location within the acute care hospital risk adjustment model, it found that in comparison to non-oncology-specific patient locations, the oncology-specific locations, particularly those designated as oncology units,[482] produced statistically significant differences in HAI measure performance. As a result, the CDC further updated the acute care risk adjustment model to stratify the HAI baselines by oncology-specific location types.[483]

[476] Centers for Disease Control and Prevention. ''Paving Path Forward: 2015 Rebase line.'' Available at: *https://www.cdc.gov/nhsn/2015rebaseline/index.html*.

[477] Ibid.

[478] Ibid.

[479] Summary of CDC's Rebaseline Analysis of NHSN HAI Data. Updated September 7, 2018.

[480] Ibid.

[481] Ibid.

[482] A ward is a floor or section of a hospital or outpatient clinic where cancer patients are treated.

[483] Summary of CDC's Rebaseline Analysis of NHSN HAI Data. Updated September 7, 2018.

(2) CAUTI and CLABSI Results Using the Updated HAI Baselines That Incorporate New Risk-Adjustment

The CDC tested the CAUTI and CLABSI measures based on the updated HAI baselines that incorporate the new risk adjustment described above. According to the CDC's calculation methodology, when assessing the performance results for the CAUTI or CLABSI measure, a p-value of 0.05 or less was noted to be statistically significant.[484] They noted that when assessed based on the adjustment for oncology unit, both the CAUTI and CLABSI measures yielded p-values of <0.0001.[485] This means that within the acute care hospital risk adjustment model, the categorization of a patient care location as an oncology unit is a statistically significant predictor of CAUTI and CLABSI incidence. Given that the majority of reporting locations within PCHs would be classified as oncology units, the application of this additional risk adjustment by location within the acute care hospital risk adjustment model will result in a more accurate assessment of the incidence of CAUTIs and CLABSIs within PCHs.

(3) Measure Applications Partnership Analysis of the Refinements to the CAUTI and CLABSI Measures

In compliance with section 1890A(a)(2) of the Act, we included the updated versions of the CAUTI and CLABSI outcome measures in a publicly available document entitled ''2019 Measures Under Consideration Spreadsheet.'' [486] This is a list of quality and efficiency measures under consideration for use in various Medicare programs, which the Measure Applications Partnership (MAP) reviews. The MAP supported the use of both refined measures in the PCHQR Program for rulemaking.[487]

Regarding the CAUTI measure, the MAP indicated that because CAUTIs are the most common HAI, hospitals should continue working to reducing their incidence and prevalence across all inpatient settings. The MAP also determined that even though CAUTI is a chart-abstracted measure that is burdensome to collect, the benefit of collecting data on this measure outweighs that cost.[488] In addition, the MAP acknowledged it is imperative to evaluate CAUTI incidence in all inpatient settings, including cancer hospitals. The revised version of this measure was endorsed by the National Quality Forum on October 23, 2019.[489] We refer readers to NQF's Final Report—Spring 2019 Cycle [490] for a more detailed discussion of this measure.

For the CLABSI measure, the MAP also determined that even though the measure is chart-abstracted and burdensome to collect, the benefit of collecting data on this measure outweighs the cost.[491] The MAP further noted that this measure is pertinent in the healthcare domain of patient safety and suggested that the CDC consider the differences in types of cancer and/or differences in types of cancer treatments when assessing the measure's performance in the future.[492] Like the CAUTI measure, we note that the revised version of this measure was endorsed by the NQF on October 23, 2019.[493] We refer readers to NQF's Final Report—Spring 2019 Cycle [494] for a more detailed discussion of this measure.

c. Summary

We are proposing to refine the CAUTI and CLABSI measures by adopting the updated measures specifications that use the new SIR calculation methodology, which calculates measure rates that are stratified by patient care locations within PCHs. We believe that it is important to continue to measure CAUTI and CLABSI incidence because of the implications these two measures have in the patient safety domain of healthcare. We also believe it is important to provide stratified performance results where appropriate for the cohort of patients with cancer which is why we believe that applying the CDC's update of the risk-adjustment model (which will ultimately yield more precise SIR results) is appropriate for the CAUTI and CLABSI measures. Implementation of the refined, stratified measures will make the measures more representative of the quality of care provided at PCHs, particularly when performance rates are compared to other acute care hospitals. Further, stratified performance results will more accurately demonstrate the incidence of CAUTI and CLABSI for comparison among PCHs. In addition, implementation of the refined versions would also address previous stakeholder requests that a statistically significant method for public reporting of these measures be utilized. Lastly, implementing the refined versions of these measures means that the PCHQR Program would be utilizing the most recently NQF-endorsed versions of these measures.

We are inviting public comment on our proposal to refine the Catheter-associated Urinary Tract Infection (CAUTI) (NQF #0138) and Central line-associated Bloodstream Infection (CLABSI) (NQF #0139) measures to utilize the updated HAI baselines that incorporate an updated risk adjustment approach, as developed by the CDC, for the FY 2023 program year and subsequent years.

4. Maintenance of Technical Specifications for Quality Measures

We maintain and periodically update technical specifications for the PCHQR Program measures. The specifications may be found on the QualityNet website at *https://www.qualitynet.org/pch*. We also refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50281), where we adopted a policy under which we use a subregulatory process to make nonsubstantive updates to measures used for the PCHQR Program. We are not proposing any changes to our processes for maintaining technical specifications for PCHQR Program measures in this proposed rule.

5. Public Display Requirements

a. Background

Under section 1866(k)(4) of the Act, we are required to establish procedures for making the data submitted under the PCHQR Program available to the public. Such procedures must ensure that a PCH has the opportunity to review the data that are going to be made public with respect to that PCH, prior to such data being made public. Section 1866(k)(4) of the Act also provides that the Secretary must report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in such hospitals on the CMS website.

[484] NHSN's Guide to the SIR-Updated March 2019. Available at: *https://www.cdc.gov/nhsn/2015rebaseline/index.html*.

[485] Ibid.

[486] 2019 Measures Under Consideration. Information available at: *http://www.qualityforum.org/Project_Pages/MAP_Hospital_Workgroup.aspx*.

[487] 2020 Considerations for Implementing Measures Draft Report—Hospitals. Available at: *http://www.qualityforum.org/map/*.

[488] Ibid.

[489] Memo CSAC Meeting—Spring 2019 Cycle, available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=86057*.

[490] Final Report—Spring 2019 Cycle, available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=86057*.

[491] 2020 Considerations for Implementing Measures Draft Report—Hospitals. Available at: *http://www.qualityforum.org/map/*.

[492] Ibid.

[493] Memo CSAC Meeting—Spring 2019 Cycle, available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=86057*.

[494] Final Report—Spring 2019 Cycle, available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=86057*.

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57191 through 57192), we finalized that although we would continue to use rulemaking to establish what year we would first publicly report data on each measure, we would publish the data as soon as feasible during that year. We also stated that our intent is to make the data available on at least a yearly basis, and that the time period for PCHs to review their data before the data are made public would be approximately 30 days in length. We announce the exact data review and public reporting timeframes on a CMS website and/or on our applicable listservs.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42520 through 42523), we finalized that we would begin to publicly display data on a number of PCH measures as soon as is practicable due to planned website improvements that we stated could delay our ability to begin the public display. In October 2019, we began to publicly report data on the following four HAI measures: (1) Specific Surgical Site Infection (SSI) Outcome Measure (NQF #0753); (2) NHSN Facility-wide Inpatient Hospital-onset Methicillin resistant Staphylococcus aureus Bacteremia Outcome Measure (NQF #1716); (3) NHSN Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717); and (4) NHSN Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431).

In the table that follows, we summarize our current public display requirements for the PCHQR Program measures.

Previously Finalized Public Display Requirements for PCHQR Program

Summary of Finalized Public Display Requirements	
Measures	**Public Reporting**
• HCAHPS (NQF #0166)** • Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology (NQF #0383)	2016 and subsequent years
• External Beam Radiotherapy for Bone Metastases (EBRT) (NQF #1822)*	2017 and subsequent years
• American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery] (NQF #0753) • National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* Bacteremia Outcome Measure (NQF #1716) • National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717) • National Healthcare Safety Network (NHSN) Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431)	2019 and subsequent years
• Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy	As soon as feasible
• CAUTI (NQF #0138) • CLABSI (NQF #0139)	Deferred until CY 2022

**Measure finalized for removal, beginning with the FY 2022 program year.*

b. Proposal To Publicly Display the Refined Versions of the CAUTI and CLABSI Measures

As described in section VIII.B.3.b. of the preamble of this proposed rule, we are proposing to adopt refined versions of the CAUTI and CLABSI measures in the PCQHR Program beginning with the FY 2023 program year. Should this proposal be finalized as proposed, we propose to begin publicly reporting the refined versions of the CAUTI and CLABSI measures in the fall of 2022 using CY 2021 data. We will not publicly report the current versions of those measures because as described above, the refined versions of the measures more accurately capture the quality of care furnished at PCHs. We welcome comment on this proposal.

6. Form, Manner, and Timing of Data Submission

Data submission requirements and deadlines for the PCHQR Program are posted on the QualityNet website. We are not proposing any updates to our previously finalized data submission requirements and deadlines in this proposed rule.

7. Extraordinary Circumstances Exceptions (ECE) Policy Under the PCHQR Program

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41623 through 41624), for a discussion of the Extraordinary Circumstances Exceptions (ECE) policy under the PCHQR Program. We are not proposing any changes to this policy in this proposed rule.

C. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

1. Background

The Long-Term Care Hospital Quality Reporting Program (LTCH QRP) is authorized by section 1886(m)(5) of the Act, and it applies to all hospitals certified by Medicare as long-term care hospitals (LTCHs). Under the LTCH QRP, the Secretary must reduce by 2 percentage points the annual update to the LTCH PPS standard Federal rate for discharges for an LTCH during a fiscal year if the LTCH has not complied with the LTCH QRP requirements specified for that fiscal year. For more information on the requirements we have adopted for the LTCH QRP, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51743 through 51744), the FY 2013 IPPS/LTCH PPS

final rule (77 FR 53614), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50853), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50286), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49723 through 49725), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57193), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38425 through 38426), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41624 through 41634), and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42524 through 42591).

2. Quality Measures Currently Adopted for the FY 2022 LTCH QRP

The LTCH QRP currently has 17 measures for the FY 2022 LTCH QRP, which are set out in the following table:

Quality Measures Currently Adopted for the FY 2022 LTCH QRP

Short Name	Measure Name & Data Source
LTCH CARE Data Set	
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)
Functional Assessment	Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631)
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	Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital (LTCH) Patients Requiring Ventilator Support (NQF #2632)
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)
Compliance with SBT	Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay
Ventilator Liberation	Ventilator Liberation Rate
TOH – Provider	Transfer of Health Information to the Provider Post-Acute Care
TOH – Patient	Transfer of Health Information to the Patient Post-Acute Care
NHSN	
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)
CLABSI	National Healthcare Safety Network (NHSN) Central Line-associated Bloodstream Infection (CLABSI) Outcome Measure (NQF #0139)
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 LTCH	Medicare Spending Per Beneficiary (MSPB)–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)
DTC	Discharge to Community–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)

Furthermore, LTCHs are required to report additional standardized patient assessment data beginning with the FY 2022 LTCH QRP. For more information on the reporting of this additional standardized patient assessment data, we refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42536 through 42590).

There are no proposals or updates in this proposed rule for the LTCH Quality Reporting Program.

3. Form, Manner, and Timing of Data Submission Under the LTCH QRP

We refer readers to the regulations at § 412.560(b) for information regarding the current policies for reporting LTCH QRP data.

For more details about the required reporting periods of measures or standardized patient assessment data during the first and subsequent years upon adoption, please refer to the FY 2020 IPPS/LTCH PPS final rule (84 FR 24588 through 24590).

5. Policies Regarding Public Display of Measure Data for the LTCH QRP

We are not proposing any new policies regarding the public display of measure data at this time.

D. Proposed Changes to the Medicare and Medicaid Promoting Interoperability Programs

1. Background

a. Statutory Authority for the Medicare and Medicaid Promoting Interoperability Programs

The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorizes incentive payments under Medicare and Medicaid for the adoption and meaningful use of certified electronic health record technology (CEHRT). Incentive payments under Medicare were available to eligible hospitals and CAHs for certain payment years (as authorized under sections 1886(n) and 1814(l) of the Act, respectively) if they successfully demonstrated meaningful use of CEHRT, which included reporting on eCQMs using CEHRT. Incentive payments were available to Medicare Advantage (MA) organizations under section 1853(m)(3) of the Act for certain affiliated hospitals that successfully demonstrate meaningful use of CEHRT. In accordance with the timeframe set forth in the statute, these incentive payments under Medicare generally are no longer available, except for Puerto Rico eligible hospitals. For more information on the Medicare incentive payments available to Puerto Rico eligible hospitals, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41672 through 41675).

Sections 1886(b)(3)(B)(ix) and 1814(l)(4) of the Act also establish downward payment adjustments under Medicare, beginning with FY 2015, for eligible hospitals and CAHs that do not successfully demonstrate meaningful use of CEHRT for certain associated EHR reporting periods. Section 1853(m)(4) of the Act establishes a negative payment adjustment to the monthly prospective payments of a qualifying MA organization if its

affiliated eligible hospitals are not meaningful users of CEHRT, beginning in 2015.

Section 1903(a)(3)(F)(i) of the Act establishes 100 percent Federal financial participation (FFP) to States for providing incentive payments to eligible Medicaid providers (described in section 1903(t)(2) of the Act) to adopt, implement, upgrade, and meaningfully use CEHRT. We previously established, however, that in accordance with section 1903(t)(5)(D) of the Act, in no case may any Medicaid eligible hospital receive an incentive after 2021 (§ 495.310(f), 75 FR 44319). Therefore, December 31, 2021 is the last date that States could make Medicaid Promoting Interoperability Program payments to Medicaid eligible hospitals (other than pursuant to a successful appeal related to 2021 or a prior year) (84 FR 42591 through 42592). For additional discussion or context around the discontinuation of the Medicaid Promoting Interoperability Program, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41676 through 41677) or the CY 2019 PFS/QPP final rule (83 FR 59704 through 59706).

2. EHR Reporting Period

a. Proposed EHR Reporting Period in CY 2022 for Eligible Hospitals and CAHs

Under the definitions of ''EHR reporting period'' and ''EHR reporting period for a payment adjustment year'' at 42 CFR 495.4, the EHR reporting period in CY 2021 is a minimum of a continuous 90-day period in CY 2021 for new and returning participants in the Promoting Interoperability Programs. Eligible hospitals and CAHs may select an EHR reporting period of a minimum of any continuous 90-day period in CY 2021 (from January 1, 2021 through December 31, 2021).

For CY 2022, we are proposing an EHR reporting period of a minimum of any continuous 90-day period in CY 2022 for new and returning participants (eligible hospitals and CAHs) in the Medicare Promoting Interoperability Program. We believe that adopting a 90-day EHR reporting period in CY 2022 as in CY 2021 would be appropriate because it would provide programmatic consistency for hospital reporting. We are proposing corresponding changes to the definition of ''EHR reporting period for a payment adjustment year'' at 42 CFR 495.4. We are not proposing to define an EHR reporting period in CY 2022 for the Medicaid Promoting Interoperability Program because the program will end with CY 2021 in accordance with section 1903(t)(5)(D) of the Act (42 CFR 495.310(f)). For additional discussion or context around the discontinuation of the Medicaid Promoting Interoperability Program, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41676 through 41677) or the CY 2019 PFS/QPP final rule (83 FR 59704 through 59706).

3. Proposed Changes to the Query of Prescription Drug Monitoring Program Measure Under the Electronic Prescribing Objective

a. Background

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41648 through 41656), we adopted two new opioid measures for the Electronic Prescribing objective, however, we changed certain policies related to those measures in the subsequent FY 2020 IPPS/LTCH PPS final rule (84 FR 42593 through 42596): (1) Query of Prescription Drug Monitoring Program (PDMP), which is optional in CY 2019 and CY 2020 and worth 5 bonus points each year; and (2) Verify Opioid Treatment Agreement, which was optional in CY 2019 but removed entirely from the program starting in CY 2020.

b. Query of PDMP Measure

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42595), we finalized that the Query of PDMP measure is optional and eligible for 5 bonus points in CY 2020. We have continued to receive substantial feedback from health IT vendors and hospitals that the flexibility currently included in the measure presents unintended challenges such as significant burden associated with IT system design and additional development needed to accommodate the measure and any future changes to it. Since publication of the FY 2020 IPPS/LTCH PPS final rule, stakeholders have continued to express concern that it is still too premature to require the Query of PDMP measure and score it based on performance in CY 2021.

We agree with stakeholders that PDMPs are still maturing in their development and use. As stated by the Substance Abuse and Mental Health Services Administration (SAMHSA) in 2018, ''PDMPs operate independently within states and are not currently linked into a larger system; therefore, no comprehensive national PDMP prescription data are available. Moreover, there is no uniform way of accessing PDMP data across states, as data platforms differ by state.'' [495]

Stakeholders also mentioned the challenge posed by the current lack of integration of PDMPs into the EHR workflow. Historically, health care providers have had to go outside of the EHR workflow in order to separately log in to and access the State PDMP. In addition, stakeholders noted the wide variation in whether PDMP data can be stored in the EHR. By integrating PDMP data into the health record, health care providers can improve clinical decision making by utilizing this information to identify potential opioid use disorders, inform the development of care plans, and develop effective interventions.

ONC recently engaged in an assessment to better understand the current state of policy and technical factors impacting PDMP integration across States. This assessment explored factors like PDMP data integration, standards and hubs used to facilitate interstate PMDP data exchange, access permissions, and laws and regulations governing PDMP data storage. The assessment revealed ambiguous or non-existent policies regarding PDMP placement in health IT systems, interpretation of PDMP data, and PDMP access roles. Less than half of hospitals have reported integration of PDMP queries within their EHR workflows.[496] In addition, variability in standards and hubs used to facilitate interstate PMDP data exchange, as well as to store and report PDMP data, contribute to the complexity of PDMPs.

The SUPPORT for Patients and Communities Act, enacted in 2018, is an important investment in combating the opioid epidemic. Several of the provisions of the SUPPORT for Patients and Communities Act address opioid use disorder prevention, recovery, and treatment, including increased access to evidence-based treatment and follow-up care, through legislative changes specific to the Medicare and Medicaid programs. Specifically, with respect to PDMPs, the SUPPORT for Patients and Communities Act included new requirements and federal funding for PDMP enhancement, integration, and interoperability, and established mandatory use of PDMPs by certain Medicaid providers to help reduce opioid misuse and overprescribing and to help promote the overall effective prevention and treatment of opioid use disorder.

Section 5042(a) of the SUPPORT for Patients and Communities Act added section 1944 to the Act, titled ''Requirements relating to qualified prescription drug monitoring programs and prescribing certain controlled

[495] *https://www.edc.org/sites/default/files/uploads/pdmp-overview.pdf.*

[496] See also ONC analysis of 2017 AHA survey data at: *https://www.healthit.gov/buzz-blog/health-it/new-data-show-nearly-one-third-of-hospitals-can-access-pdmp-data-within-their-ehr.*

substances.'' Subsection (f) of section 1944 of the Act increased Medicaid FFP during FY 2019 and FY 2020 for certain state expenditures to design, develop, or implement a qualified PDMP (and to make subsequent connections to such program). As a condition of this enhanced FFP, states must meet the conditions described in section 1944(f)(2) regarding agreements with contiguous states. There are currently a number of states that have used or are seeking to use, this enhanced FFP.

Under section 1944(b)(1) of the Act, to be a qualified PDMP, a PDMP must facilitate access by a covered provider to the following information (at a minimum) about a covered individual, in as close to real-time as possible: Information regarding the prescription drug history of a covered individual with respect to controlled substances; the number and type of controlled substances prescribed to and filled for the covered individual during at least the most recent 12-month period; and the name, location, and contact information of each covered provider who prescribed a controlled substance to the covered individual during at the least the most recent 12-month period. Under section 1944(b)(2) of the Act, a qualified PDMP must also facilitate the integration of the information described in section 1944(b)(1) of the Act into the workflow of a covered provider, which may include the electronic system used by the covered provider for prescribing controlled substances. CMS issued additional guidance to states about the enhanced FFP authorized by the SUPPORT for Patients and Communities Act, which can be found at *https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/faq051519.pdf*.

We additionally note that section 7162 of the SUPPORT for Patients and Communities Act supports PDMP integration as part of the CDC's grant programs aimed at efficiency and enhancement by states, including improvement in the intrastate and interstate interoperability of PDMPs.

In support of efforts to expand the use of PDMPs, there are currently a number of federally supported activities underway aimed at developing a more robust and standardized approach to EHR–PDMP integration. Partners including CMS, CDC, ONC, and private sector stakeholders are focused on developing and refining standard-based approaches to enable effective integration into clinical workflows, exploring emerging technical solutions to enhance access and use of PDMP data, and providing technical resources to a variety of stakeholders to advance and scale the interoperability of health IT systems and PDMPs. For instance, stakeholders are working to map the NCPDP SCRIPT standard version 2017071 and the 2015 ASAP Prescription Monitoring Program Web Service standard version 2.1A to the HL7® FHIR® standard version R4.[497] These mapping efforts are currently targeting completion by June 2020 after which the standard would be balloted. Moreover, a number of enhancements to PDMPs are occurring across the country, including enhancements to RxCheck which is a federally supported interstate exchange hub for PDMP data.[498] In addition, the ONC Interoperability Standards Advisory includes monitoring of current and emerging standards related to PDMP and OUD data capture and exchange that would allow a provider to request a patient's medication history from a State PMDP.[499] We believe these standards and technical approaches are likely to rapidly reach maturity and to support adoption across health care system stakeholders.

In addition to monitoring activities which can provide a stronger technical foundation for a measure focused on PDMP use, we also requested comments in the FY 2020 IPPS/LTCH PPS proposed rule on alternative measures designed to advance clinical goals related to the opioid crisis (84 FR 19568 and additional comment responses in the FY 2020 IPPS/LTCH PPS final rule in 84 FR 42593 through 42595). Specifically, we sought public comment on the development of potential measures for consideration for the Promoting Interoperability Program that are based on existing efforts to measure clinical and process improvements specifically related to the opioid epidemic, including opioid quality measures endorsed by the National Quality Forum (NQF) and CDC Quality Improvement (QI) opioid measures based on CDC guidelines around prescribing practices. The latter of these includes the use of electronically specific CDS to support OUD prevention and treatment best practices and the integration of a PDMP query as a part of specific clinical workflows. We stated that these measures relate to a range of activities that hold promise in combatting the opioid epidemic as part of OUD prevention and treatment best practices, that they can be supported using CEHRT, and that they may include the use of PDMP queries as a tool within the broader clinical workflows. We continue to evaluate the comments received in response to this request, and will explore how measures such as those discussed may help participants to better understand the relationship between the measure description and the use of health IT to support the actions of the measures related to opioid use.

We understand that there is wide variation across the country in how health care providers are implementing and integrating PDMP queries into health IT and clinical workflows, and that it could be burdensome for health care providers if we were to narrow the measure to specify a single approach to PDMP–EHR integration at this time. At the same time, we have heard extensive feedback from EHR developers that effectively incorporating the ability to count the number of PDMP queries in the EHR would require more robust certification specifications and standards. These stakeholders stated that health IT developers may face significant cost burdens under the current flexibility allowed for health care providers if they either fully develop numerator and denominator calculations for all the potential use cases and are required to change the specification at a later date. Stakeholders have noted that the costs of additional development will likely be passed on to health care providers without additional benefit as this development would be solely for the purpose of calculating the measure rather than furthering the clinical goal of the measure (for public comments discussed in last year's final rule, we refer readers to (84 FR 42593 through 42595), continued from last year's proposed rule in (84 FR 19556 through 19558)).

Given current efforts to improve the technical foundation for EHR–PDMP integration, the continued implementation of the SUPPORT for Patients and Communities Act (in particular, its provisions specific to Medicaid providers and qualified PDMPs), our ongoing review of alternative measure approaches, and stakeholder concerns as previously discussed about the current readiness across states for implementation of the existing measure, we believe that additional time is needed prior to requiring a Query of PDMP measure for performance-based scoring. While we appreciate the concerns that stakeholders have shared, CMS believes that this measure can play an important role in helping to address the opioid crisis. Maintaining it as an optional

[497] *http://hl7.org/fhir/us/meds/pdmp.html.*

[498] *https://www.pdmpassist.org/RxCheck.*

[499] *https://www.healthit.gov/isa/allows-a-provider-request-a-patients-medication-history-a-state-prescription-drug-monitoring.*

measure with bonus points signals to the hospital and vendor community that this is an important measure which addresses a current gap that can help to spur development and innovation to reduce the barriers and challenges expressed to CMS.

Therefore, we are proposing for CY 2021 to maintain the Electronic Prescribing Objective's Query of PDMP measure as optional and worth 5 bonus points, as well as proposing corresponding changes to the regulation at § 495.24(e)(5)(iii)(B). Continuing to include the measure as optional in CY 2021 would allow time for further progress around EHR–PDMP efforts minimizing the burden on eligible hospitals and CAHs reporting while still providing an opportunity for capable implementers to report on and earn 5 bonus points for the optional measure. We seek comments on our proposal to maintain the Query of PDMP measure in CY 2021 as optional and worth 5 bonus points.

4. Health Information Exchange Objective: Support Electronic Referral Loops by Receiving and Incorporating Health Information Measure

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41659 through 41661), we established a new Support Electronic Referral Loops by Receiving and Incorporating Health Information measure by combining the Request/Accept Summary of Care measure and the Clinical Information Reconciliation measure. In establishing the new measure, we did not change the specifications or actions associated with the two combined measures, which address receiving an electronic summary of care record and conducting reconciliation of the summary of care record. However, the name of the measure includes the word ''incorporating,'' which is not always required to increment the numerator of the measure. Instead, clinical information reconciliation must be completed using CEHRT for the following three clinical information sets: (1) Medication; (2) Medication Allergy; and (3) Current Problem List. In addition, we established that for cases in which the eligible hospital or CAH determines no update or modification is necessary within the patient record based on the electronic clinical information received, the eligible hospital or CAH may count the reconciliation in the numerator without completing a redundant or duplicate update to the record (83 FR 41661). Thus, we are proposing to modify the name of the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure to better reflect the actions required by the numerator and denominator. We are proposing to replace the word ''incorporating'' with the word ''reconciling''. The new proposed name would read: Support Electronic Referral Loops by Receiving and Reconciling Health Information measure. We are proposing corresponding changes to § 495.24(e)(6)(ii)(B).

5. Scoring Methodology for Eligible Hospitals and CAHs Attesting to CMS under the Medicare Promoting Interoperability Program for an EHR Reporting Period in CY 2021

The following table reflects the objectives and measures for CY 2021 if the proposed changes discussed previously are adopted as final, including the proposed name change to the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure and the continuation of the optional Query of PDMP measure worth 5 bonus points for CY 2021.

Performance-Based Scoring Methodology EHR Reporting Period in CY 2021

Objective	Measure	Maximum Points
Electronic Prescribing	e-Prescribing	10 points
	Bonus: Query of PDMP	5 points (*bonus*)
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points
	Support Electronic Referral Loops by Receiving and Reconciling Health Information *	20 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Choose any two: • Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Public Health Registry Reporting • Clinical Data Registry Reporting • Electronic Reportable Laboratory Result Reporting	10 Points

Notes: The Security Risk Analysis measure is required, but will not be scored.
Measure with a proposed name change in this proposed rule is denoted with an asterisk (*).

5. Clinical Quality Measurement for Eligible Hospitals and CAHs Participating in the Medicare and Medicaid Promoting Interoperability Programs

a. Background and Current Clinical Quality Measures

Under sections 1814(l)(3)(A), 1886(n)(3)(A), and 1903(t)(6)(C)(i)(II) of the Act and the definition of ''meaningful EHR user'' under 42 CFR 495.4, eligible hospitals and CAHs must report on clinical quality measures (CQMs; also referred to as electronic CQMs, or eCQMs) selected by CMS using CEHRT, as part of being a meaningful EHR user under the Medicare and Medicaid Promoting Interoperability Programs. We previously established, however, that in accordance with section 1903(t)(5)(D) of the Act, in no case may any Medicaid eligible hospital receive an incentive after 2021 (§ 495.310(f), 75 FR 44319). Therefore, December 31, 2021 is the last date that States could make Medicaid Promoting Interoperability Program payments to Medicaid eligible hospitals (other than pursuant to a successful appeal related to 2021 or a prior year) (84 FR 42591 through 42592).

The following table lists the previously finalized eCQMs available for eligible hospitals and CAHs to report under the Medicare and Medicaid Promoting Interoperability Programs (84 FR 42597 through 42599) for the reporting period in CY 2021 and in subsequent years, including the Safe Use of Opioids—Concurrent Prescribing measure (NQF #3316e), which we finalized as mandatory for reporting beginning with CY 2022.

CQMs for Eligible Hospitals and CAHs for CY 2021 and Subsequent Years

Short Name	Measure Name	NQF No.
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients (ED-2)	0497
PC-05	Exclusive Breast Milk Feeding	0480
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e

b. Proposed eCQM Reporting Periods and Criteria for the Medicare and Medicaid Promoting Interoperability Programs in CYs 2021, 2022, and 2023

Consistent with our proposal for the Hospital IQR Program elsewhere in this proposed rule, we are proposing to progressively increase the number of quarters for which hospitals are required to report eCQM data, from the current requirement of one self-selected calendar quarter of data, to four calendar quarters of data, over a three-year period. Specifically, we propose to require 2 self-selected calendar quarters of data from 2021, 3 self-selected calendar quarters of data from 2022, and 4 calendar quarters of data beginning with2023. We believe that increasing the number of quarters for which hospitals are required to report eCQM data would produce more comprehensive and reliable quality measure data for patients and providers. Taking an incremental approach over a three-year period would give hospitals and their vendors time to plan in advance and build upon and utilize investments already made in their EHR infrastructure. We refer readers to section VIII.A.10.e. of the preamble of this proposed rule for similar proposals under the Hospital IQR Program.

(1) Proposed Changes to the eCQM Reporting Period in CY 2021

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42599 through 42600), we established the eCQM reporting periods, reporting criteria, and submission periods for CY 2021. We refer readers to that final rule for a more detailed discussion of our previously established final policies. Consistent with our proposal for the Hospital IQR Program elsewhere in this rule, we are proposing to modify the CQM reporting period in CY 2021 under the Medicare and Medicaid Promoting Interoperability Programs for eligible hospitals and CAHs that report CQMs electronically. Specifically, we are proposing to require eligible hospitals and CAHs to report two self-selected calendar quarters of eCQM data from CY 2021, for four self-selected eCQMs from the set of available eCQMs for CY 2021 as previously established (84 FR 42599 through 42600). We are inviting public comment on this proposal.

(2) Proposed Changes to the eCQM Reporting Period in CY 2022

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42600), we established the eCQM reporting periods, reporting criteria, and submission periods for CY 2022. We refer readers to that final rule for a more detailed discussion of our previously established final policies. Consistent with our proposal for the Hospital IQR Program elsewhere in this rule, we are proposing to modify the eCQM reporting period in CY 2022 under the Medicare Promoting Interoperability Program for eligible hospitals and CAHs that report eCQMs electronically. Specifically, we are proposing to require eligible hospitals and CAHs to report three self-selected calendar quarters of eCQM data from CY 2022, for each required eCQM as previously established (84 FR 42600): (a) Three self-selected eCQMs from the set of available CQMs for CY 2022, and (b) the Safe Use of Opioids—Concurrent Prescribing eCQM. We are inviting public comment on this proposal.

(3) Proposed Reporting and Submission Requirements for eCQMs for CY 2023 and Subsequent Years

For CY 2023 and each subsequent year, we are proposing to require

eligible hospitals and CAHs reporting CQMs for the Medicare Promoting Interoperability Program to report four calendar quarters of data from CY 2023 and each subsequent year for: (a) Three self-selected eCQMs from the set of available eCQMs for CY 2023 and each subsequent year; and (b) the Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e), for a total of four eCQMs. As finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42601 through 42602), attestation is no longer a method for reporting CQMs for the Medicare Promoting Interoperability Program beginning with the reporting period in CY 2023, and instead, all eligible hospitals and CAHs are required to submit their eCQM data electronically through the reporting methods available for the Hospital IQR Program. Additionally, we are proposing that the submission period for the Medicare Promoting Interoperability Program would be the 2 months following the close of the respective calendar year. For example, the submission period would be the 2 months following the close of CY 2023, ending February 28, 2024. We are inviting public comment on these proposals.

b. Proposed Public Reporting of eCQM Data

Electronic reporting serves to further the CMS and HHS policy goals to promote quality through performance measurement and, in the long-term, improve the accuracy of the data and reduce reporting burden for providers. It also promotes the continued effort to align the Promoting Interoperability Program with the Hospital IQR Program. We expect that over time, hospitals will continue to leverage EHRs to capture, calculate, and electronically submit quality data, build and refine their EHR systems, and gain more familiarity with reporting eCQM data.

As eCQM reporting continues to advance, and hospitals have gained several years of experience with successfully collecting and reporting eCQM data, it is important to further our policy goals of leveraging EHR-based quality measure reporting in order to incentivize data accuracy, promote interoperability, increase transparency, and reduce long-term provider burden by providing public access to the reported eCQM data. Originally, eCQMs were integrated on a voluntary basis under the Hospital IQR Program in the FY 2014 IPPS/LTCH PPS final rule, where it was stated that additional time was required to assess the data submitted by hospitals to determine the optimal timing and transition strategy for publicly reporting eCQM data (78 FR 50813). Additionally, it was previously finalized that eCQM data would only be publicly reported if it was determined that the data was accurate enough to be reported (78 FR 50818). In the FY 2016 IPPS/LTCH PPS final rule, when the reporting of eCQMs was changed from voluntary to required, it was finalized that any data submitted electronically at that time would not be posted on the *Hospital Compare* website, and that public reporting would be addressed in future rulemaking, after the conclusion and assessment of the Hospital IQR Program's validation pilot (80 FR 49698).

Section 1886(b)(3)(B)(viii)(VII) of the Act requires the Secretary to report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in inpatient settings in hospitals on the internet website of CMS. Section 1886(b)(3)(B)(viii)(VII) of the Act also requires that the Secretary establish procedures for making information regarding measures available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. The current Hospital IQR Program policy is to report data as soon as it is feasible on CMS websites such as the *Hospital Compare* and/or its successor website after a 30-day preview period (78 FR 50776 through 50778). For additional information, please reference VIII.12.a. of this proposed rule, the Hospital IQR Program's Public Display Requirements.

Section 1886(n)(4)(B) of the Act requires the Secretary to post on the CMS website, in an easily understandable format, a list of the names of the eligible hospitals and CAHs that are meaningful EHR users, and other relevant data as determined appropriate by the Secretary. We believe other relevant data could include clinical quality measure performance rates, and data intended to improve transparency and reporting accuracy, because such data would enable patients, consumers, and health care providers to make informed decisions about their own, and their patients', healthcare. Section 1886(n)(4)(B) of the Act also requires the Secretary to ensure that an eligible hospital or CAH has the opportunity to review the other relevant data that are to be made public with respect to the eligible hospital or CAH prior to such data being made public. By publicly reporting clinical quality measure data, this demonstrates our commitment to providing data to patients, consumers, and providers as quickly as possible to assist them in their decision-making, and the effort of continual alignment with the Hospital IQR Program.

Therefore, in alignment with our goal to encourage data accuracy and transparency, we are proposing to align with the Hospital IQR Program in publicly reporting eCQM data submitted by eligible hospitals and CAHs for the Promoting Interoperability Program from the CY 2021 reporting period and subsequent years. This data could be made available to the public as early as the fall of 2022.

We are requesting public comments on these proposals, specifically, we are interested in comments that provide information on how these proposals might affect existing incentives and burdens under the Promoting Interoperability Program, as well as the benefit and utility of such data being publically available.

6. Proposed Technical Corrections to Regulation Text

a. Proposed Corrections to Regulations for Puerto Rico Eligible Hospitals Participating in the Medicare Promoting Interoperability Program

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41673 and 41674), we amended § 495.104(c)(5) to specify transition factors under section 1886(n)(2)(E)(i) of the Act for the incentive payments for Puerto Rico eligible hospitals. Although our preamble discussion of the transition factors was accurate (83 FR 41673 and 41674), our amendments to the regulation text included inadvertent technical errors. Specifically, under § 495.104(c)(5)(viii), we inadvertently included FY 2018 twice and omitted FY 2021 (83 FR 41710 and 41711). We are proposing to correct these errors by revising in future rulemaking, after the conclusion and assessment of the Hospital IQR Program's validation pilot (80 FR 49698).

§ 495.104(c)(5)(viii) to specify the correct transition factors for FYs 2018 through 2021 as follows:

- 1 for FY 2018.
- ¾ for FY 2019.
- ½ for FY 2020.
- ¼ for FY 2021.

b. Proposed Corrections to Regulatory Citations

In prior rulemaking, we adopted regulatory text at § 495.20 which cross-references ONC's certification criteria under 45 CFR 170.314. We recently identified two typographical errors in § 495.20: Specifically, paragraphs (e)(5)(iii) and (l)(11)(ii)(C)(*1*) should have cross-referenced provisions of 45 CFR 170.314, but instead certain

numbers were inadvertently transposed in the cross-references. Therefore, we are proposing to revise § 495.20(e)(5)(iii) and (l)(11)(ii)(C)(*1*) to correct these errors.

7. Future Direction of the Medicare Promoting Interoperability Program

In future years, we will continue to consider changes which support a variety of HHS goals as previously stated (83 FR 20537), including: Reducing administrative burden, supporting alignment with the Quality Payment Program, supporting alignment with the 21st Century Cures Act, advancing interoperability and the exchange of health information, and promoting innovative uses of health IT. More specifically, with regard to the 21st Century Cures Act final rule (available at *https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification*), we will take under consideration potential areas of overlap which could include: Information blocking, transitioning from the Common Clinical Data Set (CCDS) to the United States Core Data for Interoperability (USCDI), finalization of a new certification criterion for a standards-based API using FHIR, and other updates to 2015 Edition health IT certification criteria and the ONC Health IT Certification Program. We believe maintaining our focus on promoting interoperability, alignment, and simplification will reduce health care provider burden while allowing flexibility to pursue innovative applications that improve care delivery.

We solicit comment on how Medicare can best support these areas of overlap. For more detailed information on the updates discussed above, including updates made to 2015 Edition certification criteria, we refer readers to the 21st Century Cures Act final rule (available at *https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification*).

IX. Proposed Changes for Hospitals and Other Providers

A. Proposed Changes in the Submission of Electronic Patient Records to Beneficiary and Family Centered Care Quality Improvement Organizations (BFCC–QIOs)

1. Background

CMS' Quality Improvement Organization (QIO) Program is part of the HHS' national quality strategy for providing quality and patient centered care to Medicare beneficiaries. The mission of the QIO Program is to improve the effectiveness, efficiency, economy, and quality of services delivered to Medicare beneficiaries. We identify the core functions of the QIO Program as: (1) Improving quality of care for beneficiaries; (2) protecting the integrity of the Medicare Trust Fund by ensuring that Medicare pays only for services and goods that are reasonable and necessary and that are provided in the most appropriate setting; and (3) protecting beneficiaries by expeditiously addressing individual concerns (such as beneficiary complaints, provider-based notice appeals, violations of the Emergency Medical Treatment and Labor Act (EMTALA), and other related responsibilities). The QIO Program is an important resource in our effort to improve quality and efficiency of care for Medicare beneficiaries.

A QIO is an organization comprised of health quality experts, clinicians, and consumers organized to improve the quality of care delivered to people with Medicare. QIOs work under the direction of CMS, to improve the quality of healthcare for all Medicare beneficiaries, and to support the Medicare program.

Current law authorizes the QIOs to have access to the records of providers, suppliers, and practitioners under Medicare in order to perform their functions. For example, section 1154(a)(7)(C) of the Act requires QIOs, to the extent necessary and appropriate, to examine the pertinent records of any practitioner or provider of health care services that is providing services for which payment may be made under the Medicare program. Section 1156(a)(3) of the Act requires that any person who provides health care services payable under Medicare assure that services or items ordered or provided are supported by evidence of the medical necessity and quality as may reasonably be required by a reviewing QIO in the exercise of its responsibilities. Our regulations at 42 CFR 476.78(b) provide that health care providers that submit Medicare claims must cooperate in the assumption and conduct of QIO reviews. Under 42 CFR 476.78(b)(2), providers (defined broadly to include any health care facility, institution, or organization involved in the delivery of Medicare-covered services) and practitioners (defined broadly to include an individual credentialed within a recognized health care discipline and involved in providing the services of that discipline to patients) must provide patient care data and other pertinent data to the QIO when the QIO is collecting review information. In practice, this typically includes providing the QIO with copies of medical records for Medicare beneficiaries. In addition, under 42 CFR 480.111, QIOs are authorized to have access to and obtain records and information pertinent to the health care services furnished to Medicare patients, held by any institution or practitioner in the QIO area; QIOs may require the institution or practitioner to provide copies of such records or information to the QIO. In some cases, this access to information may include information from the records of non-Medicare patients.

While § 480.111 does not explicitly require submission of electronic patient records, the current regulation at § 476.78(b)(2)(ii) requires providers and practitioners to send patient records in electronic format, if available, and subject to the QIO's ability to support receipt and transmission of the electronic version of patient records. The proposed regulation change would make electronic submission the default method of submission, mandating all providers and practitioners who provide patient records to the QIO to submit them in electronic format unless they have an approved waiver. Under the proposed regulation, providers and practitioners would be required to deliver patient records within 14 calendar days of a request. We believe the QIOs have developed the capability to securely receive and transmit medical patient records in electronic format, such that requiring submission of requested patient records in electronic format by providers and practitioners who has the capability is now reasonable. This is demonstrated by the fact that QIOs currently submit case files and patient records to the Departmental Appeals Board (DAB) and the Office of Medicare Hearings and Appeals (OMHA) electronically. Based on these facts, it is now evident that all QIOs are able and capable of receiving and sending patient records in electronic format.

In 2011, we established the Medicare and Medicaid EHR Incentive Programs (now known as the Promoting Interoperability programs) to encourage eligible professionals, eligible hospitals, and critical access hospitals (CAHs) to adopt, implement, upgrade, and demonstrate meaningful use of certified electronic health record technology (CEHRT). Beginning in 2019, all eligible professionals, eligible hospitals, and CAHs are required to use CEHRT to meet the requirements of the Medicare and Medicaid Promoting Interoperability Programs. Requirements

for eligible hospitals, and CAHs that submit an attestation to CMS under the Medicare Promoting Interoperability Program were updated in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41634 through 41677). Based on the National Center for Health Statistics' 2017 National Electronic Health Records Survey, 97 percent of hospitals and 80 percent of office based physicians have adopted certified EHRs, which would enable electronic submission of records to QIOs. See: *https://www.cdc.gov/nchs/fastats/electronic-medical-records.htm.*

In § 476.1, ''provider'' is defined as a health care facility, institution, or organization, including but not limited to a hospital, involved in the delivery of health care services for which payment may be made in whole or in part under Title XVIII of the Act. The term ''practitioner'' means an individual credentialed within a recognized health care discipline and involved in providing the services of that discipline to patients. The regulations define ''QIO review'' as a review performed in fulfillment of a contract with CMS, either by the QIO or its subcontractors. The definitions specific to 42 CFR part 480 do not explicitly define the terms institution or practitioner but the context makes it clear that these terms are references to health care providers that are facilities and individual practitioners. Our proposal would address submissions of patient records by all these types of health care providers to QIOs and reimbursement for those submissions.

2. Proposed Changes

We are proposing to amend §§ 412.115, 413.355, 476.78, 480.111, and 484.265 to mandate providers and practitioners submit patient records to Beneficiary and Family Centered Care Quality Improvement Organizations (BFCC–QIOs) in an electronic format. This proposal would also update the procedures and reimbursement rates for patient records providers and practitioners furnish to QIOs. In our proposal, we use and would define the term ''patient record''. We propose to define ''patient record'' at § 476.78(e)(1) as all patient care data and other pertinent data or information relating to care or services provided to an individual patient, in the possession of the provider or practitioner, as requested by a BFCC–QIO for the purpose of performing one or more QIO functions. Providers in this context would include an institution. As discussed in more detail later in this section, we understand that QIOs request and receive primarily (if not only) records and information that is about or related to the health care provided to specific individuals. This broad definition would include any information relevant or pertinent to a particular individual (or services or Medicare-covered benefits provided to an individual) that is requested by a QIO is part of the patient record for that individual, even if the information is not necessarily part of what is traditionally understood as a medical record. We solicit comment on this definition and how we use patient record (defined this way) as the basis for reimbursement for submission of electronic patient records.

Under section 1866(a)(1)(F) of the Act, CMS is required to reimburse hospitals for the cost of providing patient records to the QIOs for QIO functions as discussed in this proposed rule. Based on similar requirements applicable to other providers and the history of litigation related to this provision, we subsequently applied this requirement to additional providers and suppliers under Medicare. The provisions governing reimbursement for sending patient records to the QIOs is codified at 42 CFR 476.78 and 42 CFR 480.111. Specifically, we are proposing the following changes to the reimbursement requirements:

- Patient records that are required to be provided to a QIO under § 476.78(b)(2) would need to be delivered in electronic format, unless a QIO approves a waiver. Providers and practitioners who lack the capability to submit patient records in an electronic format could submit patient records by facsimile or photocopying and mailing, after the QIO approves a waiver. Initial waiver requests by those providers that are required to execute a written agreement with a QIO would be expected to be made at the time the provider executes a written agreement with the QIO. Other providers and practitioners who are not required to execute a written agreement with a QIO would request a waiver by giving the QIO notice of their lack of capability to submit patient records in electronic format.
- Establish reimbursement rates of $3.00 per patient record that is submitted to the QIO in electronic format and $0.15 per page for requested patient records submitted by facsimile or by photocopying and mailing (plus the cost of first class postage for mailed photocopies), after a waiver is approved by the QIO.
- Apply those reimbursement rates to patient records submitted to a QIO in accordance with §§ 412.115, 413.355, 476.78, 480.111, and 484.265.

We believe these proposals would bring the procedures and associated reimbursement rates for submission of patient records to a QIO up to date with CMS policies for promoting use of electronic health records and burden reduction.

These proposed changes would be applicable to all providers and practitioners providing patient records to QIOs for purpose of QIO reviews under § 476.78. In addition, we are proposing to revise the requirements applicable to institutions and practitioners submitting records and information to the QIOs in accordance with § 480.111. Specifically, we are proposing to require such institutions and practitioners to conform with the requirement applicable to providers and practitioners under § 476.78(c) and (d). By the cross-references in the proposed regulation text, we are proposing to permit reimbursement by the QIOs to institutions and practitioners for providing records and information to the QIOs under § 480.111 in the same manner and rates as would apply to providers and practitioners under proposed § 476.78(e). To align with these and other changes, we are proposing also to amend other regulations that address submitting patient records for QIO reviews, specifically: §§ 412.115, 413.355, and 484.265. We address each of these proposed changes individually.

We are proposing in §§ 412.115(c), 413.355, and 484.265 to revise the current text which provides for an additional payment to be made, respectively, to hospitals, skilled nursing facilities and home health agencies in accordance with § 476.78 for the costs of photocopying and mailing medical records requested by a QIO. Specifically, we are proposing to revise these provisions to permit an additional payment to a hospital, skilled nursing facility, or home health agency in accordance with § 476.78 for the costs of sending requested patient records to the QIO in electronic format, by facsimile, or by photocopying and mailing. These changes would ensure that reimbursement is permitted for all healthcare providers and practitioners, on the same basis and at the same rates as authorized for the submission of requested patient records to the QIO under our proposed revisions to § 476.78.

The current regulation at § 476.78(c) describes the existing photocopying reimbursement methodology for prospective payment system providers and includes a step-by-step analysis of how to calculate cost of photocopying. This step-by-step analysis of how to

calculate provider's cost for photocopying records was a tool or methodology for determining or increasing reimbursement rates; we believe that specific methodology is no longer necessary in light of changes in technology and procedure. We are proposing to remove the step-by-step analysis for calculating the photocopying reimbursement rate from § 476.78(c), because we expect that 20 percent of providers would submit patient records by facsimile or photocopying and mailing if CMS authorizes reimbursement for the submission of patient records in an electronic format, and that that number would decrease further over time. The assumed 20 percent estimate of waiver requests is based on the 2017 Office of National Coordinator (ONC) and Center for Disease Control (CDC) provider and practitioner survey of EHR adoption and use of Certified EHR technology. This assumption is further supported by the number of providers that currently have access to CMS's MD portal. Therefore, we expect that future updates to the calculation of photocopying reimbursement rate would be of decreasing concern to the majority of stakeholders.

At § 476.78(c), we are proposing that information that is required to be delivered to a QIO by a provider or a practitioner under § 476.78 must be delivered in an electronic format using a mechanism specified by the requesting QIO. We propose that in the absence of a mechanism specified by the requesting QIO, the requested records may be submitted using any CMS approved secure mechanism. This includes mechanisms such as: Secure file transfer (SFT), managed file transfer (MTF), Electronic Submission of Medical Documentation System (esMD), or CMS-approved internet portal, or CMS-approved physical medium for submitting electronic records. Under our proposal, CMS would provide a list of approved mechanisms for submission of records and information to the QIO in an electronic format when the QIO contacts the provider to conduct a review, or when a written agreement between the QIO and provider is executed. We are proposing to address the amount of reimbursement in new paragraph (e) of § 476.78, as discussed later in this section. CMS would not permit the QIOs to reimburse for any patient record submitted by facsimile or by photocopying and mailing, if the provider or practitioner in question does not have an approved waiver.

We are proposing to redesignate existing § 476.78(d) as § 476.78(f), with revisions to be consistent with our proposed reimbursement rates. We propose to create a new provision at § 476.78(d) to establish a process for practitioners and providers to request waivers of the requirements for the electronic submission of requested patient records to the QIOs under proposed § 476.78(c). A QIO-approved waiver would afford a provider or practitioner who is not capable of submitting patient records to its QIO in an electronic format the opportunity to continue submitting patient records using facsimile or by photocopying and mailing. We are proposing that providers who are required to execute a written agreement with a QIO, but which lack the capability to submit requested patient records in electronic format to the requesting QIO, must request a waiver of the requirement to submit records in an electronic format to the QIO. A request for a waiver by providers who are required to execute a written agreement with the QIO, must generally be made to the QIO when executing a written agreement with the QIO. However, where such a provider's lack of capability arises after the written agreement is executed, we are proposing that the provider could request a waiver by notifying the QIO, that they lack the capability to submit patient records in electronic format. We are also proposing, at § 476.78(d)(2)(ii), that the waiver would become part of the written agreement between the QIO and the provider. Upon approval of a waiver, a provider or practitioner may submit requested patient records by facsimile or photocopying and mailing. We note that the current regulations do not specifically provide for reimbursement for patient records submitted to the QIO by facsimile, but CMS in order to encourage efficiency in patient record transmission, has historically interpreted the provisions governing reimbursement for patient records submitted to the QIOs through photocopying and mailing to also authorize reimbursement for the submission of patient records by facsimile. We are now proposing to specifically incorporate our historic interpretation into the regulatory framework. We are soliciting comment on these proposals, including the requirement that the request for a waiver must generally be made during execution of the written agreement.

Similarly, we are proposing that providers, practitioners and institutions subject to § 476.78 or § 480.111 that are not required to execute a written agreement with the QIO, may also request a waiver of the requirement to submit records in electronic format to the QIO, by notifying the QIO that they lack the capability to submit patient records in an electronic format. Upon approval of the waiver, a provider or practitioner may submit requested patient records and information by photocopying and mailing. We solicit comment on this proposal, including whether the regulation should require a written record of the waiver.

We are proposing to establish these waiver processes because we recognize that some practitioners and providers may lack the capacity to submit records to the QIOs in an electronic format. However, these providers and practitioners are still required to comply with QIO requests for records. We believe the waiver request process would not add extra burden on the providers and practitioners because they can request a waiver simply by notifying the QIO that they lack the capability to submit patient records in an electronic format, either when executing a written agreement with the QIO in accordance with § 476.78(a) or when they are contacted by the QIO to request patient records. Under our proposal, such waiver requests could be made by whatever means the provider or practitioner uses to communicate with the QIO. We invite comment on these proposals.

We are also proposing to add a new paragraph (e) to § 476.78 to authorize QIOs to reimburse providers and practitioners for the cost of submitting patient records, requested by a QIO for the purpose of carrying out QIO functions, with rates of reimbursement based on the mode of submission. The QIOs could not reimburse for any patient record submitted by facsimile or by photocopying and mailing without an approved waiver. Each of these reimbursement rates were calculated to reflect the costs associated with submitting a patient record, including labor and supplies. Proposed § 476.78(e)(2) would provide that a QIO could reimburse a provider or practitioner for requested patient records submitted in an electronic format, at the rate of $3.00 per record. We are proposing that § 476.78(e)(3) would provide that a QIO may reimburse a provider or practitioner, with an approved waiver in place, for requested patient records submitted by facsimile or photocopying and mailing at the rate of $0.15 per page, plus the cost of first class postage for patient records submitted via photocopying and mailing. We discuss the methodology, we are proposing to use to calculate these payment rates in section IX.A.2.b. of the preamble of this proposed rule.

For purposes of QIO reimbursement under § 476.78(e), we are proposing to define a ''patient record'' at § 476.78(e)(1) as all patient care data and any other pertinent data or information relating to care or services provided to an individual patient in the possession of the provider or practitioner, as requested by a QIO, for the purpose of performing one or more QIO functions. We are proposing to interpret and use this definition of patient record broadly. For example, this definition of ''patient record'' would include the policies and established operating procedures of a health care provider, to the extent that that information is pertinent to an individual patient or the services or Medicare-covered benefits provided to an individual patient, and the QIO requests that information. We are also proposing at § 476.78(e)(4) that the QIOs would only be permitted to reimburse a practitioner or providers once for each patient record submitted, for each request made by a QIO. Each request from a QIO would be reimbursed separately at the rates specified in § 476.78(e), including for records that had already been provided in response to a previous request. However, only one reimbursement would be provided by the QIO for each patient record submitted, per request, even if a particular patient record is submitted to the QIO using multiple different formats, in fragments, or more than once in response to a particular request.

We are proposing to revise the requirements applicable to institutions and practitioners submitting records and information to the QIOs in accordance with § 480.111. Specifically, we are proposing to require such institutions and practitioners to conform with the requirement applicable to providers and practitioners under § 476.78(c) and (d). By the cross-references in the proposed regulation text, we are proposing to permit reimbursement by the QIOs to institutions and practitioners for providing records and information to the QIOs under § 480.111 in the same manner and rates as would apply to providers and practitioners under proposed § 476.78(e). In our proposal, the reimbursement rates proposed under § 476.78(e) would also apply to institutions and practitioners subject to § 480.111. We are proposing to replace the current language in § 480.111(d) governing the reimbursement by the QIO for requested patient records with a provision that provides referring to the reimbursement rates in § 476.78(e). Therefore, if these changes are finalized, reimbursement for patient records submitted under § 480.111 would be consistent with reimbursement under § 476.78. This proposal would provide a consistent level of reimbursement from submission of patient records to the QIOs, across all health care providers and practitioners, that submit patient records to the QIO under §§ 476.78 and 480.111. The goal of our proposal is to put all QIO reimbursement for patient records in the same section of the regulations, so that QIOs, providers, and practitioners know where to find the relevant provisions. This proposal would also help to reduce the risk of inconsistencies in policy application due to duplication of related QIO regulations in multiple sections.

a. Required Submission of Patient Records in Electronic Format to the QIO

Currently § 476.78 requires providers and practitioners who are subject to QIO review activities under 42 CFR part 476 to submit requested patient care data and other pertinent data and information to the QIO. We are proposing to require those submissions be made in electronic format. We are proposing to require electronic submission because it is more efficient, cost effective, and timely. Our comparison of patient records submission in electronic format and submission by facsimile and mail indicate a savings of about $71.8 million to CMS over 5 years. These savings is an estimated combination of $37.6 million cost savings from reimbursement to providers for sending patient records via facsimile, photocopying and mailing, and $34.2 million cost saving from payment to QIOs to cover the costs for scanning and uploading paper based patient records.

Currently, § 476.78(b)(2)(ii) requires providers and practitioners send secure transmission of an electronic version of medical information to the QIO, if available, and subject to the QIO's ability to support receipt and transmission of the electronic version of patient records. Because most providers and all QIOs have demonstrated ability to send and receive patient records in electronic format, we are proposing to mandate providers and practitioners to submit requested patient records and information to the QIO in electronic format.

Our interoperability programs, quality reporting programs, and other programs are now requiring electronic submission of patient care data and information to CMS and its contractors. The Promoting Interoperability program is successful in encouraging widespread adoption of EHRs by providers and practitioners. In addition, about 79 percent of hospitals use the eSMD to send medical records electronically. By participation in these CMS data transfer programs, providers, practitioners, and QIOs have demonstrated the capability to collect, store, and safely transmit EHR data electronically. Based on our years of experience administering the Medicare and Medicaid EHR Incentive and Promoting Interoperability programs, we believe that most providers and practitioners are now able to safely communicate patient's medical records electronically to QIOs. This is evidenced by the increased number of providers, practitioners, and QIOs that currently participate in the use of esMD, MFT, and other related electronic data communication methods.

On September 15, 2011, we implemented the esMD system for programs requiring the review of medical documentation and patient records such as: Medicare Fee for service payment appeals, prior authorization requests, and durable medical equipment requests. The esMD system is used by providers on a voluntary basis to transmit medical documentation to review contractors electronically. This medical documentation (including patient records) is used by CMS contractors to review claims and to verify providers' compliance with Medicare rules for documentation and payment. Medicare providers and review contractors believe that using the esMD system results in cost savings and increased efficiencies, as well as improve payment turnaround time, and reduce the administrative burden associated with medical documentation requests and responses. By 2017, there are about 60,579 providers has access and used esMD to send medical records, and up to 2.5 million medical records were transmitted from providers to Medicare contractors. See 2017 esMD Annual Report: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/ESMD/Downloads/2017-esMD-Annual-Program-Report-10-01-2016-09-30-2017.pdf.*

The MFT refers to a software or a service that manages the secure transfer of data from one computer to another through a network (for example, the internet). MFT software is marketed to corporate enterprises as an alternative to using ad-hoc file transfer solutions. MFT is currently available to providers and practitioners, and QIOs currently use MFT to transmit data to its clinical peer reviewers. The MFT provides another good option for providers and practitioners to submit records and information securely to QIOs.

Given numerous improvements in electronic data communication capabilities among both providers and QIOs, and the expansion in access to electronic data communication technology, we believe it is in the best interest of the Medicare program for CMS to support electronic data communication between the QIOs and providers and practitioners. We propose to require providers and practitioners to provide patient records to the QIO electronically beginning in FY 2021 and for subsequent years. Our proposal provides for a waiver for providers and practitioners that lack the capability to submit patient records in electronic format. Lacking the capability to submit patient records in electronic format may have a number of causes, such as the records not being in an electronic format or readily convertible to an electronic format or the provider or practitioner suffering a loss of the necessary resources to submit records through the QIO-approved or CMS-approved mechanism (such as because of a power outage). The intent of this policy change is to incentivize health care providers and practitioners subject to § 476.78 to use the most efficient mechanisms available to submit required data to the QIOs for review activities, in order to minimize the time and expense required to satisfy their responsibilities under § 476.78(b), and thereby minimize the expense CMS incurs in the administering the QIO program. A complete discussion of the anticipated impact of these proposals can be found section I.H.13. of Appendix A to this proposed rule.

b. Reimbursement for Submission of Patient Records to the QIOs in Electronic Format

We are proposing at § 476.78(e)(2) to authorize the QIOs to reimburse providers and practitioners, for submitting requested patient records to the QIO in an electronic format, starting in FY 2021. The current regulation does not authorize or set a rate for reimbursement when providers submit patient records to the QIOs in an electronic format. We believe the lack of reimbursement for the submission of requested patient records in an electronic format discourages providers and practitioners from sending patient records in an electronic format, which is a more efficient and cost effective method for transmitting patient records than facsimile or photocopying and mailing. This lack of reimbursement for electronic submission of patient records does not align with other CMS programs and policies that seek to incentivize the use of electronic records and the electronic transmission of information such as the Promoting Interoperability Program. We believe this proposal would encourage more practitioners and providers to submit patient records in electronic format to the QIOs.

In calculating the rate of reimbursement for submission of patient records in an electronic format, we took into consideration the labor rate and materials cost associated with submitting patient records in an electronic format. We are proposing to follow steps similar to those used in CMS' methodology for calculating reimbursement for photocopying patient records for the QIOs. We calculated the proposed reimbursement rate for patient records submitted in electronic format as follows:

- *Step 1*—Calculate total salary of a medical records clerk, including fringe benefits, using the salary level for an experienced midlevel (GS–5 step 5) secretary in the Federal government as representative of that of a medical records clerk.
- *Step 2*—Calculate labor costs associated with searching for, downloading, and submitting electronic records.
- *Step 3*—Determine the number of patient records that can be searched, retrieved, processed, and submitted per hour.
- *Step 4*—Calculate the cost of active productive time of a medical record clerk by dividing annual salary with total productive hours, taking into account time spent at rest, and away from work.
- *Step 5*—Calculate total reimbursement for submitting patient records to the QIOs in electronic format by dividing the total productive hour cost by the total number of patient records we estimate a medical records clerk can process in 1 hour.

Using this methodology, we calculated the reimbursement for submitting records electronically to QIO as follows:

(1) The Labor Costs Associated With Searching for, Downloading, and Submitting Patient Records

Labor costs were calculated by adding the annual salary of a medical records clerk with the costs of fringe benefits, and dividing that sum with the number of patient records that can reasonably be expected to be processed in a year.

In this proposed rule, we would continue to use the salary of a Federal GS–5 midlevel secretary as representative of a medical records clerk's salary. We would take into account increases in the payment rate for a midlevel secretary in the federal government for the CY 2020. Using the salary level for an experienced midlevel (GS–5 step 5) secretary in the Federal government as representative of that of a medical records clerk, the annual salary of the medical records clerk is estimated to be $39,573 according to the Office of Personnel Management's 2020 General Schedule pay scale, with locality adjustment for the rest of the United States. In calculating the fringe benefits applicable to a medical records clerk, we used OMB Circular A–76 to calculate the annual fringe benefit cost, based on 36.25 percent of the GS–5 salary. The estimated annual fringe benefit cost is therefore $14,345 ($39,573 * 36.25 percent). Adding the fringe benefit cost, the estimated total annual salary of a medical records clerk is $53,918. Assuming a full time equivalent of 2080 hours per year and divide the annual salary by the number of hours worked ($53,918/2080 hours) in a year, the total salary per hour of a medical records clerk would be $26 per hour.

(2) Labor Costs Associated With Searching for, Downloading, and Submitting Patient Records

We assume that an average patient record request by QIO will be contained in a single electronic file that can be classified as one electronic record. This assumption is based on CMS' experience with current QIO transfer of electronic patient records to OMHA and the DAB. We estimate that it will take a medical record clerk an average of 5 minutes to search, retrieve, process, and submit a requested patient record in electronic format. Using this estimate we calculate that a medical records clerk could search for, retrieve, process, and submitted a total of 12 medical records per hour.

(3) Active Productive Time of a Medical Record Clerk

We estimate a medical records clerk is active and productive for a total of 1,430 hours per year (about 5.5 productive hours per day). We took into account the time spent by the medical records clerk at rest and lunch, and time away from work on annual vacation, sick, and holiday leave. To calculate the cost of one active productive hour we divide the estimated cost for annual salary and fringe benefits by the total number of active productive hours per year. We estimate the cost of one active productive hour at $38 per hour ($53,918/1430 hours).

(4) Cost of Supplies

We estimate that there would be no cost for supplies directly attributable to

searching, downloading, and submitting patient records to the QIO.

(5) Total Reimbursement Rate for Submitting Patient Records to the QIOs in an Electronic Format

We estimated total cost for submitting a patient record to the QIO at $3 per record. This calculation was derived by dividing the total productive hour cost of $38 by the number of patient records that can processed in an hour, which is 12 records ($38/12 records = 3.17). Consistent with our policy and generally accepted mathematics principles, we chose to round our calculations to nearest decimal. We believe this decision is both reasonable and supportable.

We invite public comment on this proposed methodology for calculating the rate of reimbursement for processing patient records in an electronic format. In addition, we invite public comment on alternative methodologies for determining more appropriate reimbursement rate for the submission of patient records to the QIOs in an electronic format, and we intend to seek to finalize our policy in the final rule based upon the public comments we received.

c. Waiver Process for Exemption From Requirement To Submit Patient Records in Electronic Format to the QIO

We propose to permit providers and practitioners who cannot submit requested patient records and information in electronic format to request a waiver. Any provider or practitioner that lacks the capability to submit patient records and information to the QIO in electronic format must obtain a waiver to be exempted from the requirement of submitting patient records and information in electronic format. Upon approval of the waiver, the provider or practitioner can submit requested patient records and information to QIO by facsimile or first class mail. We propose that requests for waivers by providers that are required to execute a written agreement with the QIO must generally be made to the QIO when executing the written agreement. After the waiver is approved, a provider or practitioner may send requested patient records and information by facsimile or first class mail. Providers and practitioners that are not required to execute a written agreement with the QIO may request a waiver to be exempted from submitting patient records in electronic format by notifying the QIO that they lack the capability to submit patient records in electronic format. The QIOs may reimburse providers and practitioners with approved waivers for requested patient records submitted by facsimile or by photocopying and mailing, as proposed in § 476.78(e)(3). Under our proposal, reimbursement would not be permitted for any patient record submitted to the QIO by facsimile or by photocopying and mailing, when the provider or practitioner does not have an approved waiver. We propose that a waiver would be approved by the QIO after the provider or practitioner has demonstrated that it lacks the capability to submit patient records in an electronic format. Under our proposal, only providers and practitioners that have an approved wavier may receive reimbursement for submitting patient records by facsimile or by photocopying and mailing.

d. Reimbursement Rate for Providers Submitting Patient Records by Photocopying and Mailing

We are proposing that the QIOs would reimburse providers with approved waivers for submitting patient record by photocopying and mailing. We are proposing at § 476.78(e)(3) to increase the reimbursement rate for submitting patient records by photocopying and mailing from $0.12 per page to $0.15 per page. We are updating this payment rate in accordance with CMS's commitment to periodically revise the photocopying reimbursement rate. This rate adjustment is fair, reasonable, and meets the current labor and material cost articulated in the established formula for calculating photocopying reimbursement rate. We propose to use the following formula for updating the rate of reimbursement for photocopying and mailing records to QIO as follows:

- *Step 1.* CMS adds the annual salary of a photocopy machine operator and the costs of fringe benefits as determined in accordance with the principles set forth in OMB circular A–76, to establish a total annual salary for the photocopy machine operator.
- *Step 2.* CMS divides the total annual salary of the photocopy machine operator by the number of pages that can be reasonably expected to be made annually by the photocopy machine operator to establish the labor cost per page.
- *Step 3.* CMS adds to the per-page labor cost as previously determined in step two to the per-page costs of photocopying supplies.

We used this methodology to determine what specific rate to propose for the reimbursement for sending patient records by photocopying and mailing patient records. We are proposing to increase the per-page reimbursement rate to $0.15 for photocopying patient records. We calculated the proposed photocopying reimbursement rate by updating the salary, fringe benefits, and supply figures associated with photocopying and submitting patient records to the QIO. In accordance with this methodology we considered the following factors in calculating the proposed new rate:

(1) Labor Costs Associated With Photocopying and Submitting Patient Records

Labor costs for photocopying patient records were calculated by adding the annual salary of a photocopy machine operator with the costs of fringe benefits, and dividing that sum by the number of pages that can reasonably be expected to be photocopied in 1 year. In this proposed rule, we would continue to rely upon the salary of a Federal GS–5 midlevel secretary as representative of a photocopy machine operator's salary. Using the salary level for an experienced (GS–5) midlevel secretary in the Federal government as representative of that of a photocopy machine operator, the annual salary of the photocopy machine operator is estimated to be $39,573, according to the Office of Personnel Management's 2020 General Schedule pay scale. This estimate include the locality pay adjustment for the rest of the United States. In calculating the fringe benefit of we used OMB Circular A–76 to calculate the annual fringe benefit cost, based on 36.25 percent of the GS–5 salary. The annual fringe benefit cost is $14,345 ($39,573 * 36.25 percent). Adding the fringe benefit, the estimated total annual salary of the photocopying operator is estimated at: $53,918. To determine the per-page labor cost, the total of salary ($39,573) and fringe benefits ($14,345) costs, which amount to $53,918, was divided by 624,000 pages, the number of photocopies a photocopy machine operator can make in 1 year. The estimated labor cost for photocopying 1 page of patient records is $0.08 ($53,918/624,000 pages).

(2) Number of Pages a Photocopy Machine Operator Can Photocopy Annually

We estimate the total number of pages that a photocopy machine operator can photocopy per year based on hand feeding of documents into a photocopying machine. We recognize that modern technologies exist which support faster photocopying, such as through automatic paper feeds. We are aware that using an automatic paper feeds can greatly increase the number of pages that can be photocopied per

minutes, and as a result, greatly decrease the cost of photocopying per page. We assume that not all providers and practitioners has access to modern technology or uses modern photocopier capable of automatic paper feed. Therefore, we would calculate the number of page a photocopy machine operator can photocopy, using the manual paper feed estimate. In calculating the number of pages that can be photocopied per hour using a manual feed, we take into consideration that recent improvements in photocopying machine technology has improved the speed of photocopier up to 8 pages per minute. In order to account for time spent by the photocopy machine operator in search and retrieval tasks, and time away from work on annual vacation, sick, and holiday leave, the total number of work hours per year is estimated at 1,300 (average of 5 productive hours per day), resulting in a total of 624,000 (1,300 hour × 60 minutes × 8 pages) pages per year.

(3) Costs of Photocopying Materials and Supplies

We are proposing a total estimated supply cost of 7 cents per page, based on a per-page paper cost of 6 cents and a per-page toner and developer cost of 1 cent per page. The supply cost include the cost of photocopying paper and toner cartridge. Using the market survey cost for these materials we estimated the average cost, using the average price and quality at the GSA material supplies rate, we estimated that copier paper cost 6 cents per page for paper and 1 cent per page for photocopy machine toner. The paper cost was based on a cost of $32.49 per case for recycled white photocopier paper of 5,000 sheets in a case. The costs of photocopier toner that yield 37,000 copies was estimated at $54.99 per toner cartridge. We calculated these costs using estimates of the costs for recycled photocopier paper and toner cartridges contained in the GSA supply catalogue.

(4) Total Reimbursement Rate for Photocopying Patient Records

We estimate total cost of photocopying at 15 cents per page. This calculation was derived by adding the total estimated labor cost of 8 cents per page and total cost of photocopying supplies of (7 cents per page. Consistent with our policy and generally accepted mathematics principles, we chose to round our calculations to nearest decimal. We believe this decision is both reasonable and supportable. We invite public comment on this proposed methodology for calculation of the rate for reimbursement for sending patient records and information by photocopying. In addition, we invite public comment on alternative methodologies for determining a more appropriate photocopying reimbursement rate and intend to finalize a policy based upon the public comments we receive.

e. Reimbursement Rate for Providers Submitting Patient Records by Facsimile

We are proposing at § 476.78(e)(3) to reimburse providers and practitioners with approved waivers that submit patient records to the QIO by facsimile at the rate of $0.15 per page. The current regulations do not specifically provide for reimbursement for patient records submitted to the QIO by facsimile, but CMS's has historically interpreted the provisions governing reimbursement for patient records submitted to the QIOs through photocopying and mailing to also authorize reimbursement for the submission of patient records by facsimile. We are now proposing to specifically incorporate our historic interpretation into the regulatory framework. Pursuant to this proposal the QIOs would continue to provide for reimbursement for patient records submitted to the QIO via facsimile, using a rate estimated based on the associated with submitting patient records to the QIO by facsimile. We believe the rate we are proposing is fair, reasonable, and reflects current labor and material costs associated with sending patient records to the QIOs by facsimile. We calculated the reimbursement for submitting patient records by facsimile to the QIO as follows:

- *Step 1.* CMS adds the annual salary of a facsimile machine operator and the costs of fringe benefits as determined in accordance with the principles set forth in OMB circular A–76, to establish a total annual salary for the facsimile machine operator.
- *Step 2.* CMS divides the total annual salary of the facsimile machine operator by the number of pages of patient records that can be reasonably expected to be sent annually by facsimile. This calculation establishes the labor cost per page of patient records submitted by facsimile.
- *Step 3.* CMS adds to the per-page labor cost as determined in step two to the average cost of maintaining a dedicated phone line for facsimile service.

We used this methodology to determine the specific rate of reimbursement we are proposing for submitting patient records to the QIO by facsimile. Similar to our methodology for calculating a fair and appropriate reimbursement rate for submitting records to the QIO via photocopying and mailing, we calculated the proposed reimbursement rate for sending patient records to the QIO by facsimile as follows:

(1) Labor Costs Associated With Submitting Patient Records by Facsimile

Labor costs were calculated by adding the annual salary of a facsimile machine operator with the costs of fringe benefits, and dividing that sum by the number of pages that a single facsimile operator can reasonably be expected to submit in a year. We are proposing to rely upon the salary of a Federal GS–5 midlevel secretary as representative of a facsimile machine operator's salary. Using the salary level for an experienced (GS–5) midlevel secretary in the Federal government as representative of that of a facsimile machine operator, the annual salary of the facsimile operator is estimated to be $39,573 according to the Office of Personnel Management's 2020 General Schedule pay scale, including the locality adjustment for the rest of the United States. In calculating the cost of fringe benefits we used OMB Circular A–76 to calculate the annual fringe benefit cost, based on 36.25 percent of the GS–5 salary. The annual estimated fringe benefit cost is $14,345 ($39,573 * 36.25 percent). With fringe benefits, we estimated total annual salary of the facsimile operator at $53,918.

(2) Number of Pages a Facsimile Operator Can Submit Annually

We estimate the total number of pages that a facsimile machine operator could submit per year based on hand feeding of documents into facsimile machine. We recognize that several modern technologies exist which support faster faxing, such as through automatic paper feeds or faxing over the internet. These technologies greatly increase the number of pages that can be submitted by facsimile on an hourly basis, and as a result, greatly decrease per page cost of submitting patient records by facsimile. However, we took into consideration the fact that not all providers and practitioners have access to the internet or modernized facsimile machines. Therefore, we are proposing to calculate the per page reimbursement rate using the manual paper feed as our guide. We estimated that a facsimile machine operator using a manual feed can submit 5 pages of patient records to the QIO in 1 minute. This estimate does not account for any delay in transmission due to poor connectivity or machine fault. In order to account for time spent by the facsimile machine

operator in search and retrieval tasks, and time away from work on annual vacation, sick, and holiday leave, we estimated the total number of work hours per year at 1,300 (an average of 5 productive hours per day), resulting in a total of 390,000 (1,300 hours × 60 minutes × 5 pages) pages of patient records, which a facsimile operator can submit to the QIO in 1 year.

To determine the per-page labor cost for submitting patient records to the QIO via facsimile, we divided the total salary ($39,573) and fringe benefits ($14,345) costs, $53,918, by 390,000, the number of copies a facsimile operator can submit in a year, resulting in an estimated labor cost of 14 cents per page ($53,918/390,000 pages).

(3) Other Costs Associated With Sending Patient Records by Facsimile

We are proposing to reimburse the cost of a dedicated telephone line used for a facsimile machine at the rate of $29.99 per month, for an estimated total cost of $359.88 per year. Our estimate does not take into consideration that multiple facsimile machines can use on telephone line, and that a telephone line can be used for other purposes than transmitting records via facsimile. We estimated that 1 cent per page ($359.88/390,000 pages) would reflect the cost of a dedicated telephone line used for facsimile service, based on estimated the estimated 390,000 pages of patient records we expect a facsimile machine operator could submit in a year. We estimated the cost of telephone line using the average per month cost for a single business telephone line per month based on an average drawn from comparison of major telecommunications service provider rates. We estimate that there is no reimbursable paper or material cost associated with sending patient records to the QIO by facsimile, as CMS does not reimburse providers and suppliers for the cost of machinery and overhead costs for submitting patient records to the QIOs.

(4) Reimbursement Rate for Sending Patient Records by Facsimile

We estimate total cost of or submitting patient records by facsimile to the QIO at 15 cents per page. This estimate was calculated by adding the total estimated labor cost of 14 cents per page, and total cost of a dedicated telephone line at 1 cent per page. Consistent with our policy and generally accepted mathematics principles, we chose to round our calculations to nearest decimal. We believe this decision is both reasonable and supportable. We invite public comment on this proposed methodology for calculating the rate for reimbursement for submitting patient records by facsimile. In addition, we invite public comment on alternative methodologies for determining an appropriate facsimile reimbursement rate and intend to finalize our policy based upon the public comments we receive.

B. Revised Regulations To Account for, and Mandate, PRRB Electronic Filing (42 CFR Part 405, Subpart R)

1. Background

Congress created the Provider Reimbursement Review Board (PRRB or Board) in 1972 to furnish providers with an independent forum for resolving payment disputes typically arising from certain Medicare Part A final determinations (usually cost report audit appeals). (See 42 U.S.C. 1395oo and 42 CFR 405.1801 and 405.1840 through 405.1873.) The Board has the full power and authority to make rules and establish procedures, not inconsistent with the law, regulations, and CMS Rulings, that are necessary or appropriate to carry out its function. (See 42 U.S.C. 1395oo(e) and 42 CFR 405.1868(a).)

On average, the PRRB receives approximately 3,000 new appeals annually. The PRRB's docket is unique and complex, so it is imperative that the Board manage its docket in the most efficient manner possible. For example, an individual provider appeal may involve one or more issues; in contrast, a group appeal involves multiple providers appealing a common issue. (See 42 U.S.C. 1395oo(b) and 42 CFR 405.1837.) In addition, many providers or issues may be transferred between the cases to create a complex web of interrelated appeals. In light of these complexities, it is imperative that the Board continue to improve the efficiencies of its processes.

Until mid-2018, appeal documents (including documents such as appeal requests, transfer requests, and position papers) could only be filed with the PRRB on paper. Over the past decade, CMS and the Board have received feedback from its stakeholders requesting an electronic filing system. On August 16, 2018, the CMS Office of Hearings (OH) and the Board released the OH Case and Document Management System (OH CDMS). OH CDMS is a web-based portal where providers can file appeals and all parties can manage their cases. Besides instantaneously accepting submissions electronically, OH CDMS releases outgoing electronic correspondence and Board decisions as well. OH CDMS enables providers and their representatives to manage their cases in real time, and it allows parties to view all documents officially filed through the system (including viewing opposing parties' submissions). When a party makes a submission, whether submitting a new appeal or taking an action on an existing case, there is an immediate system notification that confirms the submission was made. All parties on the case will then receive an email confirming the date and time of delivery. Internally, the system also serves as a daily workflow management system for the PRRB and its staff and aids the PRRB in strategically managing its docket in a more efficient manner.

The feedback we have received from active users of OH CDMS has been largely positive. We have also incorporated user suggestions to refine the system. OH CDMS offers a Help Desk, available each business day, to assist users with technical questions that may arise.

2. Technical Changes To Support Electronic Filing

To support the use of the electronic filing system, we are proposing to make technical changes throughout the regulations at 42 CFR part 405, subpart R. First, we propose to update the definitions of ''date of receipt'' and ''reviewing entity'' at 42 CFR 405.1801(a) to indicate that submissions to an electronic filing system are considered received on the date of electronic delivery. We are also proposing to add a new definition of ''in writing or written'' that indicates either of these terms means a hard copy or electronic submission. We believe these are common sense technical changes that reflect current practice and understanding. We note that we are not proposing to revise the requirement in § 405.1801(a) that the date of receipt by a party or affected nonparty of documents involved in proceedings before a reviewing entity, including the Board, is presumed to be 5 days after the date of issuance. Therefore, regardless of whether the Board issues a decision electronically or by some other means, the 5-day presumption regarding receipt by a party would continue to apply. We also propose to make technical changes throughout the subpart to replace references related to hard copy documents such as ''mail'' and ''hand delivery'' with terms that apply to both hard copy and electronic submissions. We seek comments on these changes.

We are also proposing to update 42 CFR 405.1857, related to subpoenas, so that it generally conforms to the technical changes we are proposing.

However, we are proposing to add the following statement to this section, ''If the subpoena request is being sent to a nonparty subject to the subpoena, then the subpoena must be sent by certified mail.'' This change is to ensure that the subpoena rule is in accordance with section 205(d) of the Act (Issuance of subpoenas in administrative proceedings).

3. Intention To Revise Board Instructions To Require Mandatory Electronic Submissions

As stated earlier in this preamble, the Board has the full power and authority to make rules and establish procedures, not inconsistent with the law, regulations, and CMS Rulings, that are necessary or appropriate to carry out its function. (See 42 U.S.C. 1395oo(e) and 42 CFR 405.1868(a).) It is critically important that the PRRB docket records be fully populated within OH CDMS so that the Board and its stakeholders can optimally realize the technological benefits and efficiencies of OH CDMS. Therefore, we are proposing to amend the regulations at 42 CFR 405.1843 (Parties to proceedings in a Board appeal) to make clear that parties to a Board appeal shall familiarize themselves with the instructions for handling a PRRB appeal, including any and all requirements related to the electronic or online filing of documents for future mandatory filing. This change to require electronic submissions would transform the PRRB's docket to a more efficient and less costly paperless environment, and will support a better continuity of operations posture. Accordingly, no earlier than FY 2021, the PRRB may require that all new submissions (in new and pending appeals) be filed electronically using OH CDMS. This requirement would be reflected in updated Board instructions, which are currently published at *https://www.cms.gov/Regulations-and-Guidance/Review-Boards/PRRBReview/Downloads/PRRB-Rules-August-29-2018.pdf*.

Because the Board plans to wait until at least FY 2021 to potentially require electronic filings, we believe that stakeholders would have ample time necessary to register and start using the system to the extent they have not already done so on a voluntary basis. Stakeholders can access the Electronic Filing web page located at *https://www.cms.gov/Regulations-and-Guidance/Review-Boards/PRRBReview/Electronic-Filing* to find instructions on accessing and using OH CDMS. We recommend that parties to PRRB appeals, who have not already, sign up for and begin using OH CDMS as soon as possible to allow time to become familiar with the system and to avoid any issues that may arise if signing up for the system is delayed until after use of the system becomes mandatory.

It has already been approximately 21 months since the system became operational and available to stakeholders. In this regard, we note the following:

- Many providers started using the system immediately after OH CDMS was launched.
- OH CDMS now has over 700 registered users, and continues to grow. We believe that this number of users is largely representative of the cohort of stakeholders that will use OH CDMS.
- Over 65 percent of all new appeals have been filed electronically by providers using the system.
- All government contractors that participate in PRRB appeals (including Medicare Administrative Contractors (MACs), the Cost Report Audit and Appeals contractor (CRAA), and the Appeals Support Contractor (ASC)) use the system.

Nevertheless, to provide additional notice to stakeholders, the PRRB would provide at least 60 calendar days' notice (through its instructions) before the exact date that electronic filing would become mandatory. Thus, under the proposed rule, the earliest the PRRB could publish such instructions would be October 1, 2020 and, as a result, the earliest effective date for mandatory usage of the system for PRRB appeals submissions would be November 30, 2020.

We note that making use of OH CDMS mandatory for PRRB appeals is consistent with recent revisions updating the Medicare Geographic Classification Review Board (MGCRB) regulations that similarly permit the MGCRB to require the use of OH CDMS through its instructions. The MGCRB regulatory change was published in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56928 (August 22, 2016)) and the requirement to file electronically was effective for the 2020 reclassification cycle. The transition to mandatory electronic filing of MGCRB applications went smoothly, and we received positive feedback regarding OH CDMS from the user community.

Finally, we note that the provisions governing contractor hearing officer appeals, Administrative and Judicial Review and reopenings are also found in part 405 subpart R. However, we are not proposing changes to the submission procedures for these processes at this time.

B. Proposed Revisions of Medicare Bad Debt Policy

1. Background

Under the Medicare program, beneficiaries may be responsible for payments of premiums, copayments, deductibles (including blood deductibles), and coinsurance amounts that are related to covered services (42 CFR 409.80 through 409.89). The Medicare program recognizes that a beneficiary's failure to pay a deductible or coinsurance amount could lead to non-Medicare patients bearing the related costs of covered Medicare services, a result that is barred by the prohibition of cross-subsidization detailed in 1861(v)(1)(A)(i) of the Act (s*ee also* 42 CFR 413.89(d)).

Reimbursement to providers is allowable under Medicare for beneficiaries' unpaid deductible and coinsurance amounts for covered services reimbursed by the program on the basis of reasonable cost or paid under a cost-based prospective payment system. Thus, the following amounts are not included as allowable bad debts under Medicare:

- Unpaid Medicare deductible and coinsurance amounts associated with furnishing non-covered services and services furnished to non-Medicare patients.
- Unpaid Medicare premiums and Medicare copayments [500] associated with any covered service.
- Unpaid Medicare deductible and coinsurance amounts associated with any covered services paid by the Program under a fee schedule or under a reasonable charge-based methodology including Program fee schedule payments made to physicians (including payments to providers on behalf of provider-based physicians) for professional services and fee schedule payments made to other practitioners.
- Unpaid Medicare deductible and coinsurance amounts associated with covered services paid for under a contractual capitated rate-based plan, such as but not limited to, a Medicare Advantage plan.
- Unpaid Medicare deductible and coinsurance amounts written off to charity care.

[500] While copayments and coinsurance amounts are both amounts of Medicare beneficiary cost sharing, a copayment is usually a fixed amount a beneficiary may be required to pay as their share of cost for a medical service or supply (for example, a doctor's visit, hospital outpatient visit, or prescription drug). Unpaid copayments are excluded from bad debt reimbursement. Conversely, a coinsurance amount is usually an amount a beneficiary may be required to pay as a percentage share of cost with the Medicare plan for services after the payment of any applicable deductible.

• Unpaid Medicare deductible and coinsurance amounts written off to a contractual allowance account.

In accordance with section 1861(v)(1) of the Act and regulations at § 413.89, Medicare pays some of the uncollectible deductible and coinsurance amounts to certain providers, suppliers and other entities (hereinafter collectively referred to as ''providers'') eligible to receive reimbursement for bad debt of Medicare beneficiaries. To determine if bad debt amounts are allowable, providers must meet the requirements at § 413.89, and Chapter 3, *Bad Debts, Charity and Courtesy Allowances,* of the Provider Reimbursement Manual (PRM) (CMS Pub. 15–1) (hereinafter referred to as PRM), which provides further explanation and instruction regarding the requirements for Medicare bad debt reimbursement.

The reimbursement of Medicare bad debt was not originally statutorily mandated; rather, it was first promulgated by CMS [501] in 1966 [502] shortly after the Medicare Program's inception and was thereafter set forth in the regulations.[503] Congress later statutorily created reimbursement limits on allowable Medicare bad debt under section 1861(v)(1)(T), (V) and (W) of the Act. The regulations at § 413.89(b)(1) define ''bad debts'' as amounts considered to be uncollectible from accounts and notes receivable that were created or acquired in providing services. Accounts receivable and notes receivable are designations for claims arising from the furnishing of services, and are collectible in money in the relatively near future. Similar language is set forth in the PRM, Chapter 3, Section 302.1. To be an allowable Medicare bad debt, the debt must meet all of the following criteria (see § 413.89(e) and PRM, Chapter 3, Section 308):

• The debt must be related to covered services and derived from deductible and coinsurance amounts.

• The provider must be able to establish that reasonable collection efforts were made.

• The debt was actually uncollectible when claimed as worthless.

• Sound business judgment established that there was no likelihood of recovery at any time in the future.

In 1987, Congress enacted legislation that implemented a moratorium prohibiting the Secretary and contractors from making changes to Medicare bad debt reimbursement policies that were in effect on August 1, 1987 for hospitals. This is typically referred to as the ''Bad Debt Moratorium.'' (*See* section 4008(c) of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100–203)). In section 3201 of the Middle Class Tax Relief and Job Creation Act of 2012 (Pub. L. 112–96), the Bad Debt Moratorium was repealed by Congress, effective for cost reporting periods beginning on or after October 1, 2012.

Because the bad debt moratorium is no longer in existence, we believe it is appropriate to clarify certain Medicare bad debt policies that have been the subject of litigation, and generated interest and questions from stakeholders over the past several years. Hence, this proposed rule proposes to clarify, update and codify certain longstanding Medicare bad debt principles into the regulations by revising § 413.89, ''Bad debts, charity, and courtesy allowances.'' Additionally, in this proposed rule, we would recognize the new Accounting Standards Update—Topic 606 for revenue recognition and classification of Medicare bad debts. We are also proposing technical corrections to the incorrect cross references in 42 CFR 412.622 and 417.536 to refer to the Medicare bad debt reimbursement regulation at § 413.89.

We are proposing that the clarification and codification of our longstanding Medicare bad debt policies, where indicated herein, be effective for cost reporting periods beginning before, on, and after the effective date of this rule, because of the important public interest it would serve to do so as set forth in section 1871(e)(1)(A)(ii) of the Act. These longstanding bad debt policies have existed in Medicare guidance, including the PRM, for several decades and providers and beneficiaries are familiar with and rely upon them. The clarification and codification of longstanding Medicare bad debt policies into the regulations with a retroactive effective date does not affect prior transactions or impose additional duties or adverse consequences upon providers or beneficiaries, nor does it diminish rights of providers or beneficiaries. The clarification and codification of longstanding Medicare bad debt policies into the regulations with a retroactive effective date also serves an important public interest to assist providers and beneficiaries by avoiding confusion as to which longstanding policy should be applied for which cost reporting period, as might arise if the effective date was instead proposed for cost reporting periods beginning on or after the effective date of this rule. Failing to adopt the clarification and codification of longstanding Medicare bad debt policies with a retroactive effective date might lead some providers to believe that those policies did not apply to earlier cost reporting periods, and thus might cause those providers to resubmit previously submitted cost reports. The clarification and codification of longstanding Medicare bad debt policies into the regulations with a retroactive effective date serves the important public interest of promoting fairness and economy to providers by saving them the time and resources required for such resubmissions, and by saving government resources and funds from the taxpayer-funded Medicare Trust Fund that would be expended in review of cost report resubmissions. Our specific proposals for revising our regulations are discussed in this section of this rule.

2. Proposed Revisions to Regulations

a. Reasonable Collection Effort, Non-Indigent Beneficiaries

Providers are permitted to collect unpaid Medicare cost sharing amounts from beneficiaries, unless beneficiaries have been determined to be categorically or medically needy by State Medicaid Agencies to receive medical assistance from Medicaid, or determined to be indigent by the provider for Medicare bad debt purposes. If a beneficiary's Medicare cost sharing remains unpaid, in order to claim reimbursement from Medicare for the bad debt, providers must demonstrate that they have first made a reasonable effort to collect the beneficiary's unpaid deductible and/or coinsurance amounts. (See § 413.89(e)(2) and the PRM, Chapter 3, Section 310.) This reasonable effort to collect the unpaid deductible and coinsurance amounts is, in part, based on the provider applying sound business judgment and has been a longstanding Medicare bad debt policy requirement articulated in the PRM since 1968. The PRM section 310 describes a ''reasonable collection effort'' and sets forth how providers must effectuate the reasonable collection effort, as a precondition to reimbursement of a provider's bad debt. We note that the provider's required collection efforts set forth in PRM section 310 apply only to non-indigent

[501] To implement the Medicare statute, the Social Security Administration (SSA) was reorganized and the Bureau of Health Insurance (BHI) was established on July 30, 1965. The BHI then became responsible for the development of health insurance policy before the creation of the Health Care Financing Administration (HCFA), later renamed CMS. CMS Milestones 1937–2015 (July 2015).

[502] November 22, 1966 (31 FR 14813).

[503] The current Medicare bad debt regulations were originally proposed and finalized in 1966 and codified at § 405.420.

beneficiaries; the provider's required collection efforts are different for beneficiaries who have been determined by the provider to be indigent, including medically indigent, or beneficiaries enrolled in Medicaid. In this proposed rule, we are proposing to clarify and codify the distinction between non-indigent beneficiaries and indigent beneficiaries for Medicare bad debt purposes.

Specifically, we are proposing to amend § 413.89(e)(2) by adding a new paragraph (e)(2)(i) to define, for Medicare bad debt purposes, a non-indigent beneficiary as a beneficiary who has not been determined to be categorically or medically needy by a State Medicaid Agency to receive medical assistance from Medicaid, and has not been determined to be indigent by the provider for Medicare bad debt purposes.

These proposals would be effective for cost reporting periods beginning before, on, and after the effective date of this rule because the difference in collection efforts required by a provider for indigent and non-indigent beneficiaries has existed since the promulgation of Medicare bad debt policy and the definition of a non-indigent beneficiary codifies the existing meaning of the term.

(1) Issuance of a Bill, PRM Section 310

Under Medicare bad debt policy, a provider is required to demonstrate that it has made a reasonable effort to collect beneficiaries' unpaid deductibles and coinsurance amounts. PRM section 310 sets forth that to be considered a reasonable collection effort, a provider's effort to collect Medicare deductible and coinsurance amounts must be similar to the effort the provider puts forth to collect comparable amounts from non-Medicare patients. It must involve the issuance of a bill on or shortly after discharge or death of the beneficiary to the party responsible for the patient's personal financial obligations. It also includes other actions such as subsequent billings, collection letters and telephone calls or personal contacts with this party which constitute a genuine, rather than a token, collection effort. The provider's collection effort may include using or threatening to use court action to obtain payment.

Generally, providers will have financial incentives to issue bills to patients as soon as possible to collect the outstanding debt and remove it from their financial records, or present beneficiaries' unpaid deductible and coinsurance amounts to Medicare after a reasonable collection effort period for reimbursement of the Medicare reimbursable amount.

Over the past several years, we have received feedback from stakeholders indicating that ''shortly after'' in PRM section 310 is too vague, as well as inquiries as to what timeframe ''shortly after'' means for providers to comply with the reasonable collection effort. Stakeholders have suggested that ''shortly after'' could be anywhere from 30 days to a year following the discharge or death of the beneficiary. The Merriam Webster definition of ''short(ly)'' [504] is ''not extended in time,'' ''brief,'' ''expeditious,'' or ''quick.'' Although the timeframe ''shortly after'' was drafted in the PRM section 310 decades ago with an eye toward affording flexibility to providers, inquiries from stakeholders and variances in the application of ''shortly after'' over the years have led us to believe that a more definitive timeframe should be considered while still maintaining the greatest flexibility for providers.

We believe that a timeframe of 30 or 60 days would be too short because it may not allow providers with varying billing practices the ability to issue the bill within that timeframe. A timeframe of 90 or 120 days would afford greater flexibility, as we have found this to be in the upper parameters of most providers' billing practices for the issuances of bills to patients.

In addition to the queries over the definition of ''shortly after,'' stakeholders have questioned whether the benchmark event for the issuance of the bill should be the ''discharge or death of the beneficiary,'' or some other event. Generally, Medicare fee for service claims must be filed with the appropriate Medicare claims processing contractor no later than 12 months, or 1 calendar year, after the date the services were furnished.

42 CFR 424.44. For institutional providers that have a span of dates of services (that is, from X date through X date), the ''through'' date (that is, the last day of service) is used as the date of service for the 12 month (or 1 calendar year) timeframe for a provider to timely submit a bill (CMS Pub. 100–04, section 70.4). Following the processing of the claim, the provider receives a Medicare remittance advice evidencing the claim processing. Because providers have 12 months from the date of service to timely submit a bill to Medicare, we believe that requiring a provider to issue a bill for the beneficiary's unpaid cost sharing following the ''discharge or death of the beneficiary'' is a much shorter timeframe and does not afford flexibility to the provider when the provider has a much longer timeframe of 12 months from the date a service was provided to bill Medicare in accordance with the billing requirements. We note that providers usually issue a bill to a beneficiary, or the party who is financially responsible for the beneficiary's personal financial obligations, within 120 days of death or discharge. We believe that a more flexible option could be to require the provider to issue a bill for Medicare cost sharing no later than 120 days following the provider's receipt of the Medicare remittance advice for the processed claim, because this is similar to providers' usual billing timeframes, or some other event as discussed herein.

We have received suggestions from stakeholders that the benchmark event for the provider to issue a bill to the beneficiary for Medicare cost sharing should be after the provider's receipt of payment from the beneficiary's secondary payer,[505] if any. In this instance, a beneficiary may have other insurance, secondary to Medicare that may also have a coverage liability to pay for the service provided to the beneficiary. Secondary insurance may pay some or all of the costs left after the primary insurer, Medicare, has paid (for example, deductibles and/or coinsurance amounts). In this regard, the provider must bill Medicare and the secondary payer in order to determine the beneficiary's accurate and outstanding Medicare cost sharing liability. Because there is no minimum date by which a provider must issue a bill to the party responsible for the beneficiary's cost sharing, and providers can claim Medicare bad debt in the cost reporting period in which the debt was deemed worthless, there is no disadvantage to the provider for us to adopt one or all of the aforementioned benchmark scenarios upon which a provider must issue a bill.

Longstanding Medicare bad debt policy also requires that a provider's reasonable collection effort include other actions such as subsequent billings, collection letters and telephone calls or personal contacts with this party which constitute a genuine, rather than token, collection effort.'' Additionally, providers must furnish documentation to its contractor that includes the provider's bad debt collection policy which describes the collection process for Medicare and non-Medicare

[504] *https://www.merriam-webster.com/dictionary/short.*

[505] This secondary payer is other than Medicaid for a dual eligible beneficiary.

patients; the beneficiary's account history documents which show the dates of various collection actions such as the issuance of bills to the beneficiary, follow-up collection letters, reports of telephone calls and personal contact, etc.; and the beneficiary's file with copies of the bill(s) and follow-up notices.

Therefore, we are proposing to amend § 413.89(e)(2) by adding a new paragraph (e)(2)(i)(A) to specify the reasonable collection effort requirement for a non-indigent beneficiary must be similar to the effort the provider, and/or the collection agency acting on the provider's behalf, puts forth to collect comparable amounts from non-Medicare patients. It must involve the issuance of a bill to the beneficiary or the party responsible for the beneficiary's personal financial obligations on or before 120 days after: (1) The date of the Medicare remittance advice; or (2) the date of the remittance advice from the beneficiary's secondary payer, if any; whichever is latest. A provider's reasonable collection effort also includes other actions such as subsequent billings, collection letters and telephone calls or personal contacts with this party which constitute a genuine, rather than token, collection effort. Additionally, a provider must maintain and, upon request, furnish documentation to its contractor that includes the provider's bad debt collection policy which describes the collection process for Medicare and non-Medicare patients; the beneficiary's account history documents which show the dates of various collection actions such as the issuance of bills to the beneficiary, follow-up collection letters, reports of telephone calls and personal contact, etc.; and the beneficiary's file with copies of the bill(s) and follow-up notices.

In this proposed rule, we are proposing that these revisions, except for § 413.89(e)(2)(i)(A)(*2*) and (*3*), would be effective for cost reporting periods beginning before, on and after the effective date of this rule. The provisions proposed in § 413.89(e)(2)(i)(A)(*3*), regarding the requirement to issue a bill to the beneficiary or the party responsible for the beneficiary's personal financial obligations based on the remittance advice date from Medicare or the beneficiary's secondary payer, if any, would be effective for cost reporting periods beginning on or after the effective date of this rule.

In this proposed rule, we are also proposing that the proposals for § 413.89(e)(2)(i)(A)(*2*) regarding the prior longstanding Medicare bad debt policy requiring the issuance of a bill to the beneficiary or the party responsible for the beneficiary's personal financial obligations on or shortly after discharge or death of the beneficiary would be effective for cost reporting periods beginning before the effective date of this rule.

(2) 120-Day Collection Effort and Reporting Period for Writing Off Bad Debts

Under Medicare bad debt policy, PRM section 310.2 sets forth a ''presumption of noncollectibility,'' which provides that if after reasonable and customary attempts to collect a bill, the debt remains unpaid more than 120 days from the date the first bill is mailed to the beneficiary, the debt may be deemed uncollectible.

This means that a provider must make reasonable and customary attempts to collect a bill for at least 120 days from (and including) the date the first bill is mailed to the beneficiary (or the party responsible for the beneficiary's personal financial obligations), including when a provider uses a collection agency to collect a bill. If the debt remains unpaid on the 121st day from the date the first bill is mailed to the beneficiary, the provider can cease collection efforts and presume that the account is non-collectible, and designate the unpaid deductible and coinsurance amounts as an uncollectible bad debt.

Over the past several years, questions have arisen from stakeholders with regard to the effect on the collection effort when a provider receives partial payments during the 120-day collection effort time period. We have always intended that when a partial payment is received within the required 120-day collection effort period, the collection effort is not completed and the 120-day time period restarts on the day the partial payment is received. The language in the PRM section 310.2 supports this reasoning as it sets forth ''if, after 120 days, a payment is not received, the unpaid amount can be written off.'' The corollary is that if, within the 120 days, a partial payment is received, the remaining uncollected amount cannot be written off to Medicare bad debt because the collection effort is active and ongoing by way of the response from the beneficiary submitting a payment. The partial payment received evidences the beneficiary's willingness to pay the debt, at least in part, and the provider must further engage with the beneficiary and follow up, by way of continuing the collection effort and sending additional collection letters or bills to the beneficiary for another 120-day collection effort time period. The purpose of Medicare bad debt is to reimburse providers for beneficiaries' unpaid deductibles and/or coinsurance amounts. It is reasonable to place a date of finality on the collection effort time period; hence, the 120-day minimum collection time period. However, when partial payments are received within the 120-day time period, it is reasonable to presume the remaining unpaid amount is collectible and expect the provider to continue the collection effort instead of presuming it to be non-collectible and requesting Medicare to reimburse the provider for what the beneficiary is actively engaging to pay. This rationale constitutes a reasonable collection effort as required by § 413.89(e)(2).

Requiring the 120-day collection effort timeframe to start anew when a partial payment is received during the 120 days is not burdensome to the provider and requires little additional resources from the provider because the account is still open on the provider's accounting books, and has not yet been written off as a bad debt. Additionally, because ''uncollectible deductibles and coinsurance amounts are recognized as allowable bad debts in the reporting period in which the debts are determined to be worthless,'' (PRM, Chapter 3, Section 314), the provider can claim the unpaid amounts as a Medicare bad debt after the additional 120-day collection effort time period, provided that no additional payment is received that would require an extension of the 120-day collection effort time period again.

We are proposing to amend § 413.89(e)(2) by adding a new paragraph (e)(2)(i)(A)(*5*)(*ii*) to specify that when the provider receives a partial payment within the minimum 120-day required collection effort period, the provider must continue the collection effort and the day the partial payment is received is day one of the new collection period. For each subsequent partial payment received during a 120-day collection effort period, the provider must continue the collection effort and the day the subsequent partial payment is received is day one of the new collection period. The provider is permitted to end the collection effort at the end of a 120-day collection effort period when no payments have been received during those consecutive 120 days. These revisions would be effective for cost reporting periods beginning before, on and after the effective date of this rule because we are proposing to clarify and codify our longstanding policy pertaining to the required 120-day collection effort.

In this proposed rule, we are also proposing to codify into the regulations our longstanding policy as set forth in PRM section 316, Recovery of Bad Debts, which specifies required procedures for when a provider receives a payment, or recovery, for an amount that was previously claimed as a Medicare bad debt, and paid, in a prior cost reporting period. Consistent with this proposal, we are proposing to amend § 413.89(f) by adding language to specify that, effective for cost reporting periods beginning before, on and after October 1, 2020, the deductible and coinsurance amounts uncollected from beneficiaries are to be written off and recognized as allowable bad debts in the cost reporting period in which the accounts are deemed to be worthless. Any payment on the account made by the beneficiary, or a responsible party, after the write-off date but before the end of the cost reporting period, must be used to reduce the final bad debt for the account claimed in that cost report.

In some cases an amount written off as a bad debt and reimbursed by the program in a prior cost reporting period may be recovered in a subsequent accounting period; in such situations, the recovered amount must be used to reduce the provider's reimbursable costs in the period in which the amount is recovered. However, the amount of such reduction in the period of recovery must not exceed the actual amount reimbursed by the program for the related bad debt in the applicable prior cost reporting period. Because this is has been our longstanding policy as set forth in the PRM for several decades, we are codifying this policy into the regulations to also apply to cost reporting periods beginning before, on and after the effective date of this rule.

(3) Similar Collection Effort Required, Including Collection Agency Use, PRM Section 310

Under Medicare bad debt policy, Medicare regulations at § 413.89(e)(2) require that providers engage in reasonable collection efforts. Our manual guidance currently states that, ''[t]o be considered a reasonable collection effort, a provider's effort to collect Medicare deductible and coinsurance amounts must be similar to the effort the provider puts forth to collect comparable amounts from non-Medicare patients.'' PRM section 310. As such, a provider's dissimilar debt collection practices for Medicare and non-Medicare patient accounts do not constitute a provider's ''reasonable collection effort'' to claim reimbursement from Medicare for a bad debt, whether the collection effort from the provider is an in-house collection effort or if the provider elects to refer bad debt accounts to a collection agency for an outside collection effort. This policy has been the subject of dispute by stakeholders in the past and we believe that a clarification of the policy is necessary with incorporation of the PRM guidance into the regulations.

If a provider elects to refer its non-Medicare accounts to a collection agency, the provider must similarly refer its Medicare accounts of ''like amount.'' The PRM section 310.A states that where a collection agency is used, Medicare expects the provider to refer all uncollected patient charges of like amount to the agency without regard to class of patient. The ''like amount'' requirement may include uncollected charges above a specified minimum amount. Therefore, if a provider refers to a collection agency its uncollected non-Medicare patient charges which in amount are comparable to the individual Medicare deductible and coinsurance amounts due the provider from its Medicare patient, Medicare requires the provider to also refer its uncollected Medicare deductible and coinsurance amounts to the collection agency.

When the provider uses a collection agency to perform a reasonable collection effort on its behalf, the provider must ensure that the collection agency's collection effort is similar to the effort the collection agency puts forth to collect comparable amounts from non-Medicare patients. This means that for similar, comparable amounts of the collection accounts, the collection agency must use similar collection practices for both accounts.

The collection agency's collection effort can include subsequent billings, collection letters, and telephone calls or personal contacts with the party who is financially responsible for the beneficiary's personal financial obligation which constitute a genuine, rather than a token, collection effort. The collection agency's collection effort may also include using or threatening to use court action to obtain payment. Where the collection agency does not follow the reasonable collection effort requirement, Medicare does not recognize the fees as an allowable administrative cost. Collection accounts that remain at a collection agency, for whatever reason, including accounts that are monitored passively by the collection agency, cannot be claimed by the provider as a Medicare bad debt. This is because during the period the unpaid account remains at the collection agency, the provider cannot meet the fourth regulatory requirement in § 413.89(e)(4) that ''sound business judgment established that there was no likelihood of recovery at any time in the future.'' While an account remains at a collection agency, there is always a likelihood of at least some recovery on the account. The purpose of having an account at a collection agency is to collect on the account, even if the account is in a passive collection status. Hence, the very act of having an account at a collection agency is deemed to be a collection effort undertaken by the provider. As such, the provider cannot establish that there is ''no likelihood of recovery at any time in the future'' for the account and the provider is unable to claim the account as an allowable Medicare bad debt.

The fee charged by the collection agency is its charge for providing the collection service and is not considered a Medicare bad debt. Where a provider uses the services of a collection agency and the collection agency performs a reasonable collection effort, Medicare recognizes the fees the collection agency charges the provider as an allowable administrative cost. When a collection agency obtains payment of an account receivable, the gross amount collected reduces the patient's account receivable by the same amount and must be credited to the patient's account. The collection fee deducted by the agency is charged to administrative costs.

Example 1—Collection Agency Charges Percent Fee

The provider sends a beneficiary's account of $400 to the collection agency and the collection agency's fee for its service is 30 percent of the collected amount. If the collection agency collects $220 from the beneficiary, the collection agency keeps $66 (30 percent of $220) as its fee for the collection services and remits $154 ($220 less $66) to the provider. The provider records the full amount collected by the collection agency ($220) in the beneficiary's account receivable and records the collection fee ($66) in administrative costs. Once the collection agency completes the required collection efforts on this account, returns the account back to the provider and the provider deems the account worthless, the provider can claim on its cost report the amount of $180 ($400 less $220) as a Medicare bad debt (subject to further statutorily mandated reductions as set forth in § 413.89(h)). The provider cannot claim the $66 collection agency fee as a Medicare bad debt.

Example 2—Collection Agency Charges Flat Fee

The provider sends a beneficiary's account of $400 to the collection agency and the collection agency's flat fee is $100 per account for its services. If the collection agency collects $250 from the beneficiary, the collection agency keeps $100 as its fee for the collection services and remits $150 ($250 less $100) to the provider. The provider records the full amount collected by the collection agency ($250) in the beneficiary's account receivable and records the collection fee ($100) in administrative costs. Once the collection agency completes the required collection effort on this account, returns the account back to the provider and the provider deems the account worthless, the provider can claim on its cost report the amount of $150 ($400 less $250) as a Medicare bad debt (subject to further statutory mandated reductions as set forth in § 413.89(h)). The provider cannot claim the $100 collection agency fee as a Medicare bad debt.

We therefore are proposing to amend § 413.89(e)(2) by adding a new paragraph (e)(2)(i)(A) to specify that a provider's effort to collect Medicare deductible and coinsurance amounts must be similar to the effort the provider puts forth to collect comparable amounts from non-Medicare patients. A provider's dissimilar debt collection practices for Medicare and non-Medicare patient accounts do not constitute a reasonable collection effort to claim reimbursement from Medicare for a bad debt, whether the collection effort from the provider is an in-house collection effort or if the provider elects to refer bad debt accounts to a collection agency for an outside collection effort. A provider may use a collection agency to perform a reasonable collection effort on its behalf. The provider must ensure that the collection agency's collection effort is similar to the effort the collection agency puts forth to collect comparable amounts from non-Medicare patients. The collection agency's collection effort can include subsequent billings, collection letters, and telephone calls or personal contacts with this party which constitute a genuine, rather than a token, collection effort. The collection agency's collection effort may include using or threatening to use court action to obtain payment. The fee charged by the collection agency is its charge for providing the collection service and is not considered a Medicare bad debt. Where a provider uses the services of a collection agency and the collection agency performs a reasonable collection effort, Medicare recognizes the fees the collection agency charges the provider as an allowable administrative cost. Where the collection agency does not follow the reasonable collection effort requirement, Medicare does not recognize the fees as an allowable administrative cost. Collection accounts that remain at a collection agency, for whatever reason, including accounts that are monitored passively by the collection agency, cannot be claimed by the provider as a Medicare bad debt. When a collection agency obtains payment of an account receivable, the gross amount collected reduces the patient's account receivable by the same amount and must be credited to the patient's account. The collection fee deducted by the agency is charged to administrative costs.

These revisions would be effective for cost reporting periods beginning before, on and after the effective date of this rule because we are clarifying and codifying our longstanding policy.

(4) Documentation Required—Reasonable Collection Effort for Non-Indigent Beneficiaries

Medicare's longstanding bad debt policy requires that as part of a provider's reasonable collection effort for beneficiaries, including non-indigent beneficiaries, the provider must maintain and, upon request, furnish to the Medicare contractor documentation of the provider's collection effort, whether the provider performs the collection effort in house or whether the provider uses a collection agency to perform the required collection effort on the provider's behalf. PRM section 310.B. The documentation of the collection effort must include: The provider's bad debt collection policy which describes the collection process for Medicare and non-Medicare patients; the patient account history documents which show the dates of various collection actions such as the issuance of bills, follow-up collection letters, reports of telephone calls and personal contact, etc. Unpaid deductible and coinsurance amounts without collection effort documentation are not considered as allowable bad debts.

Therefore, we propose to amend § 413.89(e)(2) by adding a new paragraph (e)(2)(i)(A)(*6*) to specify the requirements a provider must follow in order to establish the provider's reasonable collection effort for non-indigent beneficiaries.

Because these are clarifications of codifications of longstanding Medicare bad debt policy, these revisions would be effective for cost reporting periods beginning before, on and after the effective date of the final rule.

b. Reasonable Collection Effort, Beneficiaries Determined Indigent by Provider Using Required Criteria

Under PRM, Chapter 3, Section 312, a provider may determine a beneficiary to be indigent for purposes of claiming a beneficiary's unpaid deductible and/or coinsurance amounts as a Medicare bad debt. A provider can determine a beneficiary's indigence in one of two ways: (1) When the beneficiary is eligible for Medicaid as either a categorically or medically needy individual (that is, a dual eligible Medicare beneficiary); or (2) the provider determines a non-dual eligible Medicare beneficiary, to be indigent by applying the provider's customary methods for determining a patient to be indigent under the evaluation criteria in PRM section 312. A. through D. Once indigence is determined by the provider, and the provider concludes that there has been no improvement in the beneficiary's financial condition, the debt may be deemed uncollectible without the provider having to collect the unpaid Medicare cost sharing liability from beneficiaries by applying the requirements set forth in PRM section 310 for non-indigent beneficiaries.

Over the past several years, the criteria set forth in PRM section 312 regarding the determination of indigence have been the subject of litigation as questions have been raised as to whether the criteria are mandatory. In this proposed rule, we are proposing to clarify and codify our longstanding policy and criteria set forth in PRM section 312 A. through D. (setting for the requirements for a facility's determination of indigency).

Stakeholders have asked why PRM section 312.C requires that the beneficiary's total resources be considered when a provider evaluates a beneficiary's indigence. We believe that each beneficiary's unique total resources must be evaluated to determine whether a beneficiary is indigent. This evaluation must include, but is not limited to, an analysis of assets (only those convertible to cash, and unnecessary for the beneficiary's daily living), liabilities, and income and expenses, as well as any extenuating circumstances that would affect the determination of the beneficiary's indigence.

Therefore, we are proposing to amend § 413.89(e)(2) by adding new paragraph (e)(2)(ii) to define an indigent non-dual eligible beneficiary as a Medicare beneficiary who is determined to be indigent by the provider and not eligible for Medicaid as categorically or

medically needy. We are also proposing to amend § 413.89(e)(2) by adding new paragraph (e)(2)(ii)(A) to specify that to determine a beneficiary to be an indigent non-dual eligible beneficiary, the provider must apply its customary methods for determining whether the beneficiary is indigent under the following requirements: (1) The beneficiary's indigence must be determined by the provider, not by the beneficiary; that is, a beneficiary's signed declaration of their inability to pay their medical bills and/or deductibles and coinsurance amounts cannot be considered proof of indigence; (2) the provider must take into account a beneficiary's total resources which includes, but is not limited to, an analysis of assets (only those convertible to cash and unnecessary for the beneficiary's daily living), liabilities, and income and expenses. While a provider must take into account a beneficiary's total resources in determining indigence, any extenuating circumstances that would affect the determination of the beneficiary's indigence must also be considered; and (3) the provider must determine that no source other than the beneficiary would be legally responsible for the beneficiary's medical bill; for example, a legal guardian.

We are also proposing to amend § 413.89(e)(2) by adding new paragraph (e)(2)(ii)(B) to specify that as part of its determination of indigence, the provider must maintain and furnish, upon request to its Medicare contractor, documentation (for example, a Policy for Determination of Indigence) describing the method by which indigence or medical indigence was determined and the beneficiary specific documentation which supports the provider's documentation of each beneficiary's indigence or medical indigence. Once indigence is determined and the provider concludes that there has been no improvement in the beneficiary's financial status, the bad debt may be deemed uncollectible without applying a collection effort. Unpaid deductible and coinsurance amounts without the provider's documentation of its determination of indigence will not be considered as allowable bad debts.

In this proposed rule, we are proposing that these revisions would be effective for cost reporting periods beginning before, on and after the effective date of this rule because they are clarifications and codifications of longstanding Medicare policies.

c. Reasonable Collection Effort, Dual Eligible Beneficiaries and the Medicaid Remittance Advice

Dual eligible beneficiaries are Medicare beneficiaries who are enrolled in Medicare (either Part A, Part B, or both), and are also enrolled in ''full Medicaid'' coverage and/or the Medicare Savings Program (MSP).[506] Authorized under sections 1902 (a)(10)(E) and 1905(p) and (s) of the Act, the MSP includes four mandatory Medicaid eligibility groups that assist low income Medicare beneficiaries with their Medicare expenses.[507] One specific category of MSP is the Qualified Medicare Beneficiaries (QMB) program. Under 1905(p)(1) of the Act, a QMB is an individual who is entitled to hospital insurance benefits under Part A of Medicare, with income not exceeding 100 percent of the Federal poverty level, and resources not exceeding three times the SSI limit.

Section 1902(a)(10)(E) of the Act directs State Medicaid Agencies to pay providers for QMB cost sharing amounts as defined in section 1905(p)(3) of the Act. Under section 1905(p)(3) of the Act, ''Medicare cost sharing'' includes costs incurred with respect to a QMB, ''without regard to whether the costs incurred were for items and services for which medical assistance is otherwise available under the plan.'' The ''Medicare cost sharing'' includes Medicare Part A and B coinsurance and deductibles. Section 1902(n)(2) of the Act permits the State to limit payment for QMB cost sharing to the amount necessary to provide a total payment to the provider (including Medicare, Medicaid, required nominal Medicaid copayments, and third party payments) equal to the amount a State would have paid for the service under the state plan.

State Medicaid Management Information Systems (MMIS), funded under section 1903(a)(3) of the Act are required, as an express condition of a State receiving enhanced federal matching funds for the design, development, installation and administration of their MMIS systems, to process Medicare crossover [508] claims, including QMB cost sharing, for adjudication of Medicaid payment of Medicare cost sharing amounts, including deductibles and coinsurance for Medicare services. The MMIS is also required to furnish the provider with a Medicaid remittance advice (RA), a document that outlines the State's cost sharing liability for a particular service or set of services for the patient/beneficiary.[509] The Medicaid RA will also show whether the State has no liability for Medicare cost sharing for a beneficiary's service pursuant to the State plan.[510] The MMIS must process all Medicare crossover claims for QMBs, including Medicare-adjusted claims that are submitted by Medicaid-enrolled providers, even if a service or provider category is not currently recognized in the Medicaid State Plan. However, we recognize that there may be instances where the Medicare crossover claim process does not occur automatically and providers must instead submit their Medicare claims manually to Medicaid for adjudication and determination of the state's cost sharing liability. The most direct and logical way to know a State's cost sharing liability for a QMB is from the Medicaid RA. If a State Medicaid program had Medicare cost sharing responsibility and refused to pay, or failed to process a Medicare crossover claim to determine its cost sharing liability, it would be out of compliance with its Medicaid State plan and would be subject to enforcement action by CMS.

A State's requirement to determine its cost sharing liability for QMBs was also set forth at section 3490.14(A) of the State Medicaid Manual (SMM) (CMS Pub. 45); Payment of Medicare Part A and Part B Deductibles and Coinsurance—State Agency Responsibility, when paper claims were submitted by Medicare providers to the State to determine its cost sharing liability. Specifically, section 3490.14(A)(1) and (2) of the SMM required the State Agency to provide, through the State Plan, the payment rates applicable for services that are either covered or not covered by the State Plan, in order to determine the

[506] ''Full Medicaid'' coverage refers to the package of services, beyond coverage of Medicare premiums and cost-sharing, that certain individuals are entitled to when they qualify under eligibility groups covered under a state's Medicaid program.

[507] The MSP includes the Qualified Medicare Beneficiary, Specified Low-Income Medicare Beneficiary Qualifying Individual, and Qualified Disabled and Working Individual programs. Depending upon the MSP group the individual is enrolled in, the MSP pays all or some of an individual's Medicare expenses, including Parts A and B premiums, deductibles, coinsurance and copayments.

[508] ''Crossover'' claims are initiated when a Medicare certified provider submits a claim to its Medicare contractor for processing of the Medicare covered service and the claim ''crosses over'' to Medicaid for the State to determine and set forth the State's cost sharing liability towards beneficiaries' Medicare cost sharing. This crossover claim includes the primary payment amount from Medicare.

[509] *http://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-06-07-2013.pdf.*

[510] *http://www.medicaid.gov/Federal-Policy-Guidance/downloads/CIB-06-07-2013.pdf.*

amount of Medicare coinsurance and deductibles that the State was responsible to pay. Because a QMB's financial situation and Medicaid eligibility status may change over the course of a very short period of time and the State is required to maintain the most current patient eligibility and financial information, the State is in the best position to fulfill its statutory requirement and make the most accurate determination of its cost sharing liability for any unpaid Medicare deductibles and coinsurance.

Providers are prohibited under section 1902(n)(3) of the Act from seeking to collect payment from a QMB for Medicare deductibles or coinsurance, even if the Medicaid State plan's cost sharing liability is less than the total amount of the Medicare deductibles and coinsurance. Medicare may reimburse providers who provide Medicare covered services to dual eligible beneficiaries the difference between beneficiaries' unpaid Medicare cost sharing and the State's Medicare cost sharing liability for the beneficiary, up to the allowable Medicare bad debt amount if the provider has made a reasonable collection effort. To satisfy the reasonable collection effort, a provider that has furnished services to a dual eligible beneficiary must determine whether the State's Title XIX Medicaid Program (or a local welfare agency, if applicable) is responsible to pay all or a portion of the beneficiary's Medicare deductible and/or coinsurance amounts. A provider satisfies this by billing the State or State designee such as a Medicaid managed care organization (MCO), to determine any Medicare cost sharing amounts for which the State may be liable to the provider. This is known as the ''must-bill policy'' for dual eligible beneficiaries and is outlined in PRM sections 312 and 322.

In accordance with PRM section 312, providers seeking Medicare reimbursement for bad debts for dual eligible beneficiaries' cost sharing are required to: (1) Bill the State Medicaid program to determine that no source other than the patient would be legally responsible for the patient's medical bill; for example, title XIX, local welfare agency and guardian (the ''must bill requirement''); and (2) obtain and submit to the Contractor, a Medicaid RA from the State Medicaid program (the ''RA requirement''). The must-bill policy and the RA requirement to document the States' cost sharing liability are both longstanding policies of CMS, as shown in PRM sections 312 and 322 themselves: Administrative decisions applying the policies; and section 4499, exhibit 15.08 of the Medicare Intermediary Manual (CMS Pub. 13–4) (December 1985).

It has always been our position that the must-bill policy and the RA requirement are necessary to ensure that the provider obtains contemporaneous documentation that can be maintained in the usual course of the provider's business as required by § 413.20(a). The historical background of the RA requirement is also set forth in PRM section 322, Medicare Bad Debts Under State Welfare Programs:

Thus, when Medicare certified providers provide services to QMBs and claim bad debt to Medicare for unpaid cost sharing amounts, Medicare bad debt policy requires providers to bill the State and submit to their contractors the Medicaid RA as documentation to evidence the State's liability for dual eligible beneficiaries' deductible and/or coinsurance amounts. If a provider does not bill the State and submit the Medicaid RA to Medicare with its claim for bad debt reimbursement for dual eligible beneficiaries, the result is that unpaid deductible and coinsurance amounts cannot be included as an allowable Medicare bad debt.

In 2003, the Medicare ''must bill'' policy was upheld by the 9th Circuit Court of Appeals in *Community Hospital of the Monterey Peninsula* v. *Thompson,* including the use of a Medicaid RA to determine the State's liability. *Community Hosp. of Monterey Peninsula* v. *Thompson,* 323 F.3d 782 (9th Cir. 2003). In August 2004, CMS issued a Joint Signature Memorandum (''JSM'') 370, reiterating the ''must bill'' policy for dual eligible beneficiaries. Specifically, the JSM 370 reiterated that where the State owes none or only a portion of the dual eligible beneficiary's deductible or coinsurance, the unpaid cost sharing for the beneficiary is not reimbursable to the provider by Medicare until the provider bills the State, and the State refuses payment by producing a Medicaid RA.

In October 2004, we issued a newsletter that reiterated and clarified the contents of the JSM by stating that in instances where the State owes none or only a portion of the dual eligible patient's deductible or copayment, the unpaid liability for the bad debt is not reimbursable to the provider by Medicare until the provider bills the State, and the State refuses payment (with a State Remittance Advice).

In order to satisfy the regulatory requirement that a bad debt is uncollectible, the provider must bill the State Medicaid Agency and receive a Medicaid RA that contains a formal denial from the State or a statement setting forth the State's cost sharing liability. A State's failure to process a bill for determination of its cost sharing equates to a provider's failure to determine the cost sharing liability of the State. The burden remains on the provider to work with the State to determine the State's cost sharing amounts. This burden is not transferred to the Medicare program and the Medicare program has no duty to determine a State's cost sharing liability. A provider cannot substitute an estimate of the State's cost sharing liability for the Medicaid RA, as this does not satisfy the regulatory requirement of demonstrating that the bad debt is uncollectible. Any amount that the State is obligated to pay, either by statute or under the terms of its approved Medicaid State plan, will not be included as an allowable Medicare bad debt, regardless of whether the State actually pays its obligated amount to the provider. However, the deductible and/or coinsurance amount, or any portion thereof, that the State is not obligated to pay and which remains unpaid by the beneficiary can be included as an allowable Medicare bad debt.

Prior to the implementation of automated claims processing, section 3490.14(B) of the SMM previously provided a mechanism whereby providers could bill the State for the determination of the State's cost sharing amounts without actually being or becoming a Medicaid provider. In accordance with section 3490.14(B), ''Subject to State law a provider has the right to accept a patient either as private pay only, as a QMB only, or (if the patient is both a QMB and Medicaid eligible) as a full Medicaid patient, but the provider must advise the patient, for payment purposes, how he/she is accepted. Medicaid payment of Medicare deductible and coinsurance amounts may be made only to Medicaid participating providers, even though a Medicare service may not be covered by the Medicaid State plan. A provider agreement necessary for participation for this purpose (for example, for furnishing the services to the individual as a QMB) may be executed through the submission of a claim to the Medicaid agency requesting Medicaid payment for Medicare deductibles and coinsurance for QMBs.'' Although this SMM provision is no longer in effect, we believe State Medicaid Agencies have a statutory obligation to determine any Medicare cost sharing for QMBs, however some States do not recognize certain Medicare provider types or services under the State Medicaid program and do not process Medicare

crossover claims and issue a Medicaid RA.

Some States' noncompliance with the statutory requirement to process Medicare crossover claims and produce a Medicaid RA have resulted in numerous appeals filed by providers whose claims for reimbursement of unpaid Medicare cost sharing from services provided to dual eligible beneficiaries were denied for Medicare bad debt reimbursement because the State did not process the Medicare crossover claim and issue a Medicaid RA to the provider.

In 2013, CMS attempted to address States' non-compliance with the Federal statutory requirements at sections 1902(a)(10)(E), 1902(n) and 1903(a)(3) of the Act, by issuing an Informational Bulletin,[511] which reminded States of the Federal statutory requirement to process Medicare cost sharing claims for QMBs from Medicare-certified providers, and to be able to document proper processing of such claims. A State's non-compliance with the Federal statutory requirements conflicts with Medicare's must bill policy, resulting in the State's non-compliance and leaving providers disadvantaged.

We continue to believe that the best documentation to evidence States' cost sharing liability for a dual eligible beneficiary is the Medicaid RA, and that the Medicare requirements for the provider to bill the State and submit the RA to its contractor should remain. Where the State processes a Medicare crossover claim and issues a Medicaid RA to the provider that details the State's Medicare cost sharing liability, we believe that providers must continue to provide the Medicaid RA in order to claim Medicare bad debt. Therefore, we are proposing that the provider must bill that State and submit the Medicaid RA to Medicare to evidence the State's Medicare cost sharing liability, so that any State Medicare cost sharing liability can be deducted from the Medicare bad debt reimbursement.

Consistent with this proposal, we are proposing to amend § 413.89(e)(2) by adding a new paragraph (e)(2)(iii) to clarify and codify that that, effective for cost reporting periods beginning on and before the effective date of this rule, to be considered a reasonable collection effort, a provider that has furnished services to a dual eligible beneficiary must determine whether the State's Title XIX Medicaid Program (or a local welfare agency, if applicable) is responsible to pay all or a portion of the beneficiary's Medicare deductible and/or coinsurance amounts. To make this determination, the provider must submit a bill to its Medicaid/title XIX agency (or to its local welfare agency) to determine the State's cost sharing obligation to pay all or a portion of the applicable Medicare deductible and coinsurance. (This is effectuated by the provider submitting a bill to Medicare for payment and the MAC administering the payment process automatically 'crosses over' the bill to the applicable Medicaid/title XIX agency for determination of the State's obligation, if any, toward the cost sharing.) The provider must then submit to its contractor a Medicaid RA reflecting the State's payment decision. Any amount that the State is obligated to pay, either by statute or under the terms of its approved Medicaid State plan, will not be included as an allowable Medicare bad debt, regardless of whether the State actually pays its obligated amount to the provider. However, the Medicare deductible and/or coinsurance amount, or any portion thereof that the State is not obligated to pay, can be included as an allowable Medicare bad debt. A provider's failure to bill the State and produce to its Medicare contractor documentation, including the RA reflecting the State's verification that it processed a bill to determine its liability, will result in unpaid deductible and coinsurance amounts not being included as an allowable Medicare bad debt. Unpaid deductible and coinsurance amounts without collection effort documentation will not be considered as allowable bad debts.

We are proposing that these revisions be effective for cost reporting periods beginning before, on and after the effective date of this rule because they clarify and codify our longstanding policy to require that the provider effectuate a reasonable collection effort by billing the party (state) responsible for the Medicare cost sharing of the beneficiary. The result of the provider billing the State and the State processing the Medicare crossover claim is the provider's receipt of the Medicaid RA which is necessary to evidence the State's Medicare cost sharing liability.

Although the best documentation to evidence a State's Medicare cost sharing liability for a dual eligible beneficiary is the Medicaid RA, we acknowledge that challenges exist for providers when States do not comply with the Federal statutory requirements. So as not to disadvantage providers in States that are not in compliance with the Federal statute, we are considering alternatives for providers to comply with the ''must bill'' policy and still evidence a State's cost sharing liability (or absence thereof) for dual eligible beneficiaries when a State does not process a Medicare crossover claim and issue a Medicaid RA to providers that could be finalized in the final rule. For example, alternative documentation to a Medicaid RA could be obtained by providers from a State that demonstrates it will not enroll the provider in Medicaid, or a certain class of a type of provider, for the limited purpose of processing a claim for determining cost sharing liability. Providers could obtain alternative documentation to a RA such as a State Medicaid notification where the State has no legal obligation to pay the beneficiary's Medicare cost sharing. In a State that has a Medicare cost sharing liability for a beneficiary's service, the Medicaid State Plan may set forth the Medicare cost sharing liability for particular services. Alternatively, in a State that has a Medicare cost sharing liability for a beneficiary's service, the State could obtain alternative documentation to a Medicaid RA that sets forth the State's Medicare cost sharing liability that would then be deducted from the provider's Medicare bad debt reimbursement. In addition to verifying the state's cost sharing liability, it will also be important that any alternative documentation to a Medicaid RA accurately verifies a beneficiary's eligibility for Medicaid for the date of service. We are considering adopting a policy in the final rule to the effect that when a State does not process a Medicare crossover claim and issue a Medicaid RA, the provider could obtain, and submit to its Medicare contractor, some form of alternative documentation to evidence a state's Medicare cost sharing liability (or absence thereof). We welcome suggestions from stakeholders regarding the best alternative documentation to the Medicaid RA that a provider could obtain and submit to Medicare to evidence a beneficiary's Medicaid eligibility for the date of service and the State's Medicare cost sharing liability (or absence thereof) and regarding whether we should or could adopt such a policy effective for past cost reporting periods, including whether doing so would serve an important public interest by allowing providers with cases currently pending before the PRRB an avenue for timely and cost-effective resolution.

d. Accounting Standard Update Topic 606 and Accounting for Medicare Bad Debt

(1) Accounting Standard Update Topic 606

The principles of cost reimbursement require that providers maintain

[511] *https://www.medicaid.gov/federal-policy-guidance/downloads/cib-06-07-2013.pdf.*

sufficient financial records and statistical data for proper determination of costs payable under the program. § 413.20(a). Additionally, providers must use standardized definitions and follow accounting, statistical, and reporting practices that are widely accepted in the hospital and related fields. § 413.20(a). Medicare accounting standards follow the general accounting standards unless the Secretary declares otherwise on a particular matter. § 413.20(a). The regulations at § 413.89(c) provide that normal accounting treatment: Reduction in revenue. Bad debts, charity, and courtesy allowances represent reductions in revenue. The failure to collect charges for services furnished does not add to the cost of providing the services. Such costs have already been incurred in the production of the services. In this regard, providers are required to record bad debts and uncollectible accounts as a direct reduction of net patient revenue rather than an operating expense in their financial records.

Additionally, PRM section 314 Accounting Period for Bad Debts, provides further guidance to providers for the accounting treatment of Medicare bad debts and sets forth that ''Uncollectible deductibles and coinsurance amounts are recognized as allowable bad debts in the reporting period in which the debts are determined to be worthless. Allowable bad debts must be related to specific amounts which have been determined to be uncollectible. Since bad debts are uncollectible accounts receivable and notes receivable, the provider should have the usual accounts receivable records-ledger cards and source documents to support its claim for a bad debt for each account included.'' PRM section 314. PRM section 320 sets forth methods of determining bad debt expense, where ''accounts receivable are analyzed and a determination made as to specific accounts which are deemed uncollectible. The amounts deemed to be uncollectible are charged to an expense account for uncollectible accounts. The amounts charged to the expense account for bad debts should be adequately identified as to those which represent deductible and coinsurance amounts applicable to beneficiaries and those which are applicable to other than beneficiaries or which are for other than covered services. Those bad debts which are applicable to beneficiaries for uncollectible deductible and coinsurance amounts are included in the calculation of reimbursable bad debts.''

The Financial Accounting Standards Board's (FASB) Accounting Standards Update (ASU) 2014–09, Revenue from Contracts with Customers (Topic 606), (hereinafter ''ASU Topic 606''), was published in May 2014 with the first implementation period in 2018. Under the ASU Topic 606, there are changes in the national accounting standard for revenue recognition of patient-related bad debts and uncollectible accounts, as well as changes to terminology regarding bad debts. These changes are for all industries and organizations nationwide, including the healthcare sector and providers. Under the ASU Topic 606, an amount representing a bad debt would generally no longer be reported separately as an operating expense in the provider's financial statements, but will be treated as an ''implicit price concession,'' and included as a reduction in patient revenue. Additionally, under the ASU Topic 606 standards, bad debts are now considered to be ''reductions in patient revenue'' instead of ''uncollectible accounts receivable and notes receivable'' in accordance with the current language in PRM section 316. Additionally, under the ASU Topic 606 standards, the provider should have the usual ''accounting recordations for the reductions in revenue'' instead of ''accounts receivable records ledger cards'' pursuant to the current language in PRM section 316.

Although ASU Topic 606 requires different reporting of providers and terminology for bad debts (implicit price concessions), there is no change in the required criteria a provider must meet to qualify a beneficiary's bad debt account for Medicare bad debt reimbursement under § 413.89. Therefore, in this proposed rule, we are proposing to recognize the ASU Topic 606 terminology in § 413.89. Specifically, we are proposing to recognize that bad debts, also known as ''implicit price concessions,'' are amounts considered to be uncollectible from accounts that were created or acquired in providing services. ''Implicit price concessions'' are designations for uncollectible claims arising from the furnishing of services, and may be collectible in money in the relatively near future and are recorded in the provider's accounting records as a component of net patient revenue.

We are proposing to amend § 413.89(b)(1) by adding new paragraph (b)(1)(i) to specify that for cost reporting periods beginning before October 1, 2020, bad debts are amounts considered to be uncollectible from accounts and notes receivable that were created or acquired in providing services. ''Accounts receivable'' and ''notes receivable'' are designations for claims arising from the furnishing of services, and are collectible in money in the relatively near future. Consistent with this proposal, we are also proposing to amend § 413.89(b)(1) by adding new paragraph (b)(1)(ii) to specify that for cost reporting periods beginning on or after October 1, 2020, bad debts, also known as ''implicit price concessions,'' are amounts considered to be uncollectible from accounts that were created or acquired in providing services. ''Implicit price concessions'' are designations for uncollectible claims arising from the furnishing of services, and may be collectible in money in the relatively near future and are recorded in the provider's accounting records as a component of net patient revenue. We are also proposing to amend § 413.89(c) by adding new paragraph (c)(1) to specify that effective for cost reporting periods beginning before October 1, 2020 bad debts, charity, and courtesy allowances represent reductions in revenue. The failure to collect charges for services furnished does not add to the cost of providing the services. Such costs have already been incurred in the production of the services. We are also proposing to amend § 413.89(c) by adding new paragraph (c)(2) to specify that, effective for cost reporting periods beginning on or after October 1, 2020, bad debts, also known as ''implicit price concessions,'' charity, and courtesy allowances represent reductions in revenue. The failure to collect charges for services furnished does not add to the cost of providing the services. Such costs have already been incurred in the production of the services.

(2) Medicare Bad Debt and Contractual Allowances

Medicare regulations require providers to follow standardized definitions, accounting, statistics, and reporting practices that are widely accepted in the hospital and related fields. PRM section 320 sets forth methods of determining bad debt expense, where accounts receivable are analyzed and a determination made as to specific accounts which are deemed uncollectible. The amounts deemed to be uncollectible are charged to an expense account for uncollectible accounts. The amounts charged to the expense account for bad debts should be adequately identified as amounts that represent deductible and coinsurance amounts applicable to Medicare beneficiaries, including QMBs, amounts that are applicable to non-beneficiaries, or amounts that are for other than covered services. Those bad debts which are applicable to Medicare

beneficiaries, including QMBs, for uncollectible deductible and coinsurance amounts are included in the calculation of reimbursable bad debts.''

Based on recent questions received, it appears that many providers are not accurate in their accounting classification method of writing-off a beneficiary's deductible and coinsurance amounts for Medicare-Medicaid crossover claims, by incorrectly writing off Medicare-Medicaid crossover bad debts to a contractual allowance account. Contractual allowances, also known as contractual adjustments, are the difference between what a healthcare provider bills for the service rendered versus what it will contractually be paid (or should be paid) based on the terms of its contracts with third-party insurers and/or government programs.[512] Some providers have been writing Medicare-Medicaid crossover bad debt amounts off to a contractual allowance account because they are unable to bill the beneficiary for the difference between the billed amount and the Medicaid claim payment amount. Other providers are writing these amounts off to a contractual allowance account because the Medicaid remittance advice referenced the unpaid amount as a ''Medicaid contractual allowance.''

These Medicare-Medicaid crossover claim amounts do not meet the classification requirements for a Medicare bad debt as set forth in PRM section 320 and are not compliant with § 413.20 because these amounts were written off to a contractual adjustment or allowance account instead of a bad debt expense account.

In this proposed rule, we are proposing to clarify that Medicare bad debts must not be written off to a contractual allowance account but must be charged to an expense account for uncollectible accounts (bad debt or implicit price concession). Consistent with this proposal, we are proposing to amend § 413.89(c) by adding paragraph (c)(3) to specify that, effective for cost reporting periods beginning on or after October 1, 2020, Medicare bad debts must not be written off to a contractual allowance account but must be charged to an expense account for uncollectible accounts (bad debt or implicit price concession).

e. Technical Corrections in 42 CFR Parts 412 and 417

A technical correction is required for 42 CFR 412.622(b)(2)(i) which incorrectly refers to 42 CFR 413.80 instead of the correct citation of § 413.89, which is the regulation that sets forth rules pertaining to the bad debts of Medicare beneficiaries.

A technical correction is also required for 42 CFR 417.536(g) which incorrectly refers to § 413.80 instead of the correct citation of § 413.89, which sets forth that bad debts, charity, and courtesy allowances are deductions from revenue and are not to be included in allowable costs.

X. MedPAC Recommendations

Under section 1886(e)(4)(B) of the Act, the Secretary must consider MedPAC's recommendations regarding hospital inpatient payments. Under section 1886(e)(5) of the Act, the Secretary must publish in the annual proposed and final IPPS rules the Secretary's recommendations regarding MedPAC's recommendations. We have reviewed MedPAC's March 2020 ''Report to the Congress: Medicare Payment Policy'' and have given the recommendations in the report consideration in conjunction with the proposed policies set forth in this proposed rule. MedPAC recommendations for the IPPS for FY 2021 are addressed in Appendix B to this proposed rule.

For further information relating specifically to the MedPAC reports or to obtain a copy of the reports, contact MedPAC at (202) 653–7226, or visit MedPAC's website at: *http://www.medpac.gov*.

XI. Other Required Information

A. Publicly Available Files

IPPS-related data are available on the internet for public use. The data can be found on the CMS website at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Following is a listing of the IPPS-related data files that are available.

Commenters interested in discussing any data files used in construction of this proposed rule should contact Michael Treitel at (410) 786–4552.

1. CMS Wage Data Public Use File

This file contains the hospital hours and salaries from Worksheet S–3, parts II and III from FY 2017 Medicare cost reports used to create the proposed FY 2021 IPPS wage index. Multiple versions of this file are created each year. For a discussion of the release of different versions of this file, we refer readers to section III.L. of the preamble of this proposed rule.

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html*.

Periods Available: FY 2007 through FY 2021 IPPS Update.

2. CMS Occupational Mix Data Public Use File

This file contains the CY 2016 occupational mix survey data to be used to compute the occupational mix adjusted wage indexes. Multiple versions of this file are created each year. For a discussion of the release of different versions of this file, we refer readers to section III.L. of the preamble of this proposed rule.

Media: internet at: *https://www.cms.gov/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html*.

Period Available: FY 2021 IPPS Update.

3. Provider Occupational Mix Adjustment Factors for Each Occupational Category Public Use File

This file contains each hospital's occupational mix adjustment factors by occupational category. Two versions of these files are created each year to support the rulemaking.

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-AService-Payment/AcuteInpatientPPS/Wage-Index-Files.html*.

Period Available: FY 2021 IPPS Update.

4. Other Wage Index Files

CMS releases other wage index analysis files after each proposed and final rule.

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html*.

Periods Available: FY 2005 through FY 2021 IPPS Update.

5. FY 2021 IPPS FIPS CBSA State and County Crosswalk

This file contains a crosswalk of State and county codes used by the Federal Information Processing Standards (FIPS), county name, and a list of Core-Based Statistical Areas (CBSAs).

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* (on the navigation panel on the left side of the page, click on the FY 2021 proposed rule home page or the FY 2021 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html*.

[512] *https://www.lbmc.com/blog/contractual-allowance-for-healthcare-providers.*

Period Available: FY 2021 IPPS Update.

6. HCRIS Cost Report Data

The data included in this file contain cost reports with fiscal years ending on or after September 30, 1996. These data files contain the highest level of cost report status.

Media: internet at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Cost-Reports-by-Fiscal-Year.html*.

(We note that data are no longer offered on a CD. All of the data collected are now available free for download from the cited website.)

7. Provider-Specific File

This file is a component of the PRICER program used in the MAC's system to compute DRG/MS–DRG payments for individual bills. The file contains records for all prospective payment system eligible hospitals, including hospitals in waiver States, and data elements used in the prospective payment system recalibration processes and related activities. Beginning with December 1988, the individual records were enlarged to include pass-through per diems and other elements.

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ProspMedicareFeeSvcPmtGen/psf_text.html*.

Period Available: Quarterly Update.

8. CMS Medicare Case-Mix Index File

This file contains the Medicare case-mix index by provider number based on the MS–DRGs assigned to the hospital's discharges using the GROUPER version in effect on the date of the discharge. The case-mix index is a measure of the costliness of cases treated by a hospital relative to the cost of the national average of all Medicare hospital cases, using DRG/MS–DRG weights as a measure of relative costliness of cases. Two versions of this file are created each year to support the rulemaking.

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html*, or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or fiscal year final rule home page desired).

Periods Available: FY 1985 through FY 2021.

9. MS–DRG Relative Weights (Also Table 5—MS–DRGs)

This file contains a listing of MS–DRGs, MS–DRG narrative descriptions, relative weights, and geometric and arithmetic mean lengths of stay for each fiscal year. Two versions of this file are created each year to support the rulemaking.

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html*, or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or the fiscal year final rule home page desired).

Periods Available: FY 2005 through FY 2021 IPPS Update.

10. IPPS Payment Impact File

This file contains data used to estimate payments under Medicare's hospital inpatient prospective payment systems for operating and capital-related costs. The data are taken from various sources, including the Provider-Specific File, HCRIS Cost Report Data, MedPAR Limited Data Sets, and prior impact files. The data set is abstracted from an internal file used for the impact analysis of the changes to the prospective payment systems published in the **Federal Register**. Two versions of this file are created each year to support the rulemaking.

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Historical-Impact-Files-for-FY-1994-through-Present.html,* or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or fiscal year final rule home page desired).

Periods Available: FY 1994 through FY 2021 IPPS Update.

11. AOR/BOR Tables

This file contains data used to develop the MS–DRG relative weights. It contains mean, maximum, minimum, standard deviation, and coefficient of variation statistics by MS–DRG for length of stay and standardized charges. The BOR tables are ''Before Outliers Removed'' and the AOR is ''After Outliers Removed.'' (Outliers refer to statistical outliers, not payment outliers.)

Two versions of this file are created each year to support the rulemaking.

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html*, or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or fiscal year final rule home page desired).

Periods Available: FY 2005 through FY 2021 IPPS Update.

12. Prospective Payment System (PPS) Standardizing File

This file contains information that standardizes the charges used to calculate relative weights to determine payments under the hospital inpatient operating and capital prospective payment systems. Variables include wage index, cost-of-living adjustment (COLA), case-mix index, indirect medical education (IME) adjustment, disproportionate share, and the Core-Based Statistical Area (CBSA). The file supports the rulemaking.

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* (on the navigation panel on the left side of the page, click on the FY 2021 proposed rule home page or the FY 2021 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html*.

Period Available: FY 2021 IPPS Update.

13. MS–DRG Relative Weights Cost Centers File

This file provides the lines on the cost report and the corresponding revenue codes that we used to create the 19 national cost center cost-to-charge ratios (CCRs) that we used in the relative weight calculation.

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* (on the navigation panel on the left side of the page, click on the FY 2021 proposed rule home page or the FY 2021 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html*.

Period Available: FY 2021 IPPS Update.

14. Hospital Readmissions Reduction Program Supplemental File

Updated data are not available at this time. Therefore, we refer readers to the FY 2020 IPPS/LTCH PPS final rule supplemental file, which has the most recent finalized payment adjustment factor components and is the same data as would have been used to create the FY 2021 IPPS/LTCH PPS proposed rule supplemental file.

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* (on the navigation panel on the left side of the page, click on the FY 2021 proposed rule home page or the FY 2021 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html*.

Period Available: FY 2021 IPPS Update.

15. Medicare Disproportionate Share Hospital (DSH) Supplemental File

This file contains information on the calculation of the uncompensated care payments for FY 2021. Variables include the data used to determine a hospital's share of uncompensated care payments, total uncompensated care payments and estimated per claim uncompensated care payment amounts. The file supports the rulemaking.

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* (on the navigation panel on the left side of the page, click on the FY 2021 proposed rule home page or the FY 2021 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html*.

Period Available: FY 2021 IPPS Update.

16. New Technology Thresholds File

This file contains the cost thresholds by MS–DRG that are generally used to evaluate applications for new technology add-on payments for the fiscal year that follows the fiscal year that is otherwise the subject of the rulemaking. As we discuss in section II.F.5.i. of the preamble of this proposed rule, we are proposing to apply the proposed threshold value for proposed new MS–DRG 018 in evaluating the cost criterion for the CAR T-cell therapy technologies for purposes of FY 2021 new technology add-on payments. As also discussed in section II.G.5.i of the preamble of this proposed rule, beginning with FY 2022, we are proposing to use the proposed threshold values associated with the proposed rule for that fiscal year to evaluate the cost criterion for all other applications for new technology add-on payments and previously approved technologies that may continue to receive new technology add-on payments, if those technologies would be assigned to a proposed new MS–DRG for that same fiscal year. (We note that the information in this file was previously provided in Table 10 of the annual IPPS proposed and final rules (83 FR 41739).)

Media: internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* (on the navigation panel on the left side of the page, click on the applicable fiscal year's proposed rule or final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html*.

Periods Available: For FY 2021 and FY 2022 applications.

B. Collection of Information Requirements

1. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In this proposed rule, we are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

2. ICRs Regarding PRRB Electronic Filing (§§ 405.1801 Through 405.1889)

As stated earlier in section IX.B.3 of the preamble of this proposed rule, we propose to amend the regulations at 42 CFR 405.1801 through 405.1889 to allow the PRRB to make use of the system mandatory in PRRB appeals. Proposed § 405.1801 states that except for subpoena requests being sent to a nonparty pursuant to § 405.1857(c), the reviewing entity may prescribe the method(s) by which a party must make a submission, including the requirement to use an electronic filing system for submission of documents. Proposed amendments to the regulations at 42 CFR 405.1843 make clear that parties to a Board appeal must familiarize themselves with the instructions for handling a PRRB appeal, including any and all requirements related to the electronic or online filing of documents for future mandatory filing.

The burden associated with the requirements in discussed in this section is the time and effort necessary to review instructions and register for the electronic submission system as well as the time and effort to gather develop and submit various documents associated with a PRRB appeal. While these requirements impose burden, we believe the requirements are exempt from the PRA in accordance with the implementing regulations of the PRA at 5 CFR 1320.4. Information collected during the conduct of a criminal investigation or civil action or during the conduct of an administrative action, investigation, or audit involving an agency against specific individuals or entities is not subject to the PRA.

3. ICRs for Requests for Changes to the Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications

As discussed in section II.D. of the preamble of this proposed rule, the public may request changes to the MS–DRG classifications to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. The burden associated with requesting changes to the MS–DRG classifications will be discussed in a forthcoming information collection request, which is currently under development. However, upon completion of the ICR, we will publish the required 60-day and 30-day notices to solicit public comments in accordance with the requirements of the PRA.

4. ICRs Relating to the Hospital Readmissions Reduction Program

In section IV.K. of the preamble of this proposed rule, we discuss proposed requirements for the Hospital Readmissions Reduction Program. In this proposed rule, we are not removing or adopting any new measures into the Hospital Readmissions Reduction Program. All six of the Hospital

Readmissions Reduction Program's measures are claims-based measures. We do not believe that continuing to use these claims-based measures creates or reduces any burden for hospitals because they will continue to be collected using Medicare FFS claims that hospitals are already submitting to the Medicare program for payment purposes.

5. ICRs for the Hospital Value-Based Purchasing (VBP) Program

In section IV.L. of the preamble of this proposed rule, we provide estimated and newly established performance standards for the Hospital VBP Program for certain measures for the FY 2023, FY 2024, FY 2025, and FY 2026 program years. We do not believe that updating program performance standards will create or reduce any burden for hospitals. Data submissions for the Hospital VBP Program are associated with the Hospital Inpatient Quality Reporting Program under OMB control number 0938–1022, the National Healthcare Safety Network under OMB control number 0920–0666, and the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey under OMB control number 0938–0981. Because the FY 2023 Hospital VBP Program will use data that are also used to calculate quality measures in other programs and Medicare fee-for-service claims data that hospitals are already submitting to CMS for payment purposes, the program does not anticipate any change in burden associated with this proposed rule.

6. ICRs Relating to the Hospital-Acquired Condition (HAC) Reduction Program

In section IV.M. of the preamble of this proposed rule, we discuss proposed requirements for the HAC Reduction Program. In this proposed rule, we are not proposing to remove any measures or adopt any new measures into the HAC Reduction Program. The HAC Reduction Program has adopted six measures. We do not believe that the claims-based CMS PSI 90 measure in the HAC Reduction Program creates or reduces any burden for hospitals because it is collected using Medicare FFS claims hospitals are already submitting to the Medicare program for payment purposes. We note the burden associated with collecting and submitting data for the HAI measures (CDI, CAUTI, CLABSI, MRSA, and Colon and Abdominal Hysterectomy SSI) via the NHSN system is captured under a separate OMB control number, 0920–0666 (expiration November 30, 2021), and therefore will not impact our burden estimates.

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41478 through 41484), we finalized our policy to validate NHSN HAI measures under the HAC Reduction Program, which will require hospitals to submit validation templates for the NHSN HAI measures beginning with Q3 CY 2020 discharges. OMB has currently approved 43,200 hours of burden and approximately $1.6 million under OMB control number 0938–1352 (expiration date January 31, 2021), accounting for information collection burden experienced by up to 600 IPPS hospitals selected for validation under the HAC Reduction Program for the FY 2023 program year and each subsequent year. In section IV.M.6. of the preamble of this proposed rule, we propose to change the pool of hospitals selected for validation under the HAC Reduction Program from up to 600 hospitals to up to 400 hospitals, as similarly proposed under the Hospital IQR Program, as discussed in section VIII.A. of the preamble of this proposed rule. In this FY 2021 IPPS/LTCH PPS proposed rule, we are updating our burden calculation using the most recent data from the Bureau of Labor Statistics, which reflects a median hourly wage of $19.40 [513] per hour for a Medical Records and Health Information Technician professional. We calculate the cost of overhead, including fringe benefits, at 100 percent of the hourly wage estimate, consistent with the previous year. This is necessarily a rough adjustment, both because fringe benefits and overhead costs 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 ($19.40 × 2 = $38.80) to estimate total cost is a reasonably accurate estimation method. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of $38.80 per hour.

We previously estimated a reporting burden of 80 hours (20 hours per record × 1 record per hospital per quarter × 4 quarters) per hospital selected for validation per year to submit the CLABSI and CAUTI templates, and 64 hours (16 hours per record × 1 record per hospital per quarter × 4 quarters) per hospital selected for validation per year to submit the MRSA and CDI templates for a total of 43,200 hours ([80 hours × 300 hospitals] + [64 hours × 300 hospitals]). Based on our proposals in this proposed rule, we estimate a new total burden of 28,800 hours ([80 hours per hospital to submit CLABSI and CAUTI templates × 200 hospitals selected for validation] + [64 hours per hospital to submit MRSA and CDI templates × 200 hospitals selected for validation]), reflecting a total burden decrease of 14,400 hours (43,200 hours − 28,800 hours), and a new total burden cost of approximately $1,117,440 (28,800 hours × $38.80 per hour).[514] We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1352.

7. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

a. Background

The Hospital IQR Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program) was originally established to implement section 501(b) of the MMA, Public Law 108–173. OMB has currently approved 1,612,710 hours of burden and approximately $60.7 million under OMB control number 0938–1022, accounting for information collection burden experienced by approximately 3,300 IPPS hospitals and 1,100 non-IPPS hospitals for the FY 2022 payment determination. In this proposed rule, we describe the burden changes with regard to collection of information under OMB control number 0938–1022 (expiration date December 31, 2022) for IPPS hospitals due to the proposed policies in this proposed rule.

In section VIII.A.5.b. of the preamble to this proposed rule, we are proposing to progressively increase the numbers of quarters of eCQM data reported, from one self-selected quarter of data to four quarters of data over a 3-year period, by requiring hospitals to report two quarters of data for the CY 2021 reporting period/FY 2023 payment determination, three quarters of data for the CY 2022 reporting period/FY 2024 payment determination, and four quarters of data beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years. We expect these policies will increase our collection of information burden estimates. Details on these policies as well as the expected burden changes are discussed further in this section of this rule.

[513] Occupational Employment and Wages. Available at: *https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.*

[514] Occupational Employment and Wages. Available at: *https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.*

In section VIII.A. of the preamble to this proposed rule, we are proposing to begin public display of eCQM data beginning with data reported by hospitals for the CY 2021 reporting period and for subsequent years. As discussed further in this proposed rule, we do not expect this policy to affect our information collection burden estimates.

In section VIII.A.11. of the preamble to this proposed rule, we also are proposing several changes to streamline validation processes under the Hospital IQR Program. We are proposing to: (1) Require the use of electronic file submissions via a CMS-approved secure file transmission process and no longer allow the submission of paper copies of medical records or copies on digital portable media such as CD, DVD, or flash drive; starting with validation affecting the FY 2024 payment determination; (2) combine the validation processes for chart-abstracted measures and eCQMs for validation affecting the FY 2024 payment determination by: (a) Aligning data submission quarters; (b) combining hospital selection, including: (i) Reducing the pool of hospitals randomly selected for chart-abstracted measure validation; and (ii) integrating and applying targeting criteria for eCQM validation; (c) removing previous exclusion criteria; and (d) combining scoring processes by providing one combined validation score for the validation of chart-abstracted measures and eCQMs with the eCQM portion of the combined score weighted at zero; and (3) formalize the process for conducting educational reviews for eCQM validation affecting the FY 2023 payment determination in alignment with current processes for providing feedback for chart-abstracted validation results. As discussed further in this proposed rule, we expect our proposed policy to align the hospital selection process will increase our information collection burden estimates. We do not expect the other proposed validation policies to affect our information collection burden estimates. Details on these policies as well as the expected burden changes are discussed further in this section of this rule.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42602 through 42605), we estimated that reporting measures for the Hospital IQR Program could be accomplished by staff with a median hourly wage of $18.83 per hour. We note that since then, more recent wage data have become available, and we are updating the wage rate used in these calculations in this proposed rule. The most recent data from the Bureau of Labor Statistics reflects a median hourly wage of $19.40 per hour for a Medical Records and Health Information Technician professional.[515] We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($19.40 × 2 = $38.80) to estimate total cost is a reasonably accurate estimation method. Accordingly, we will calculate cost burden to hospitals using a wage plus benefits estimate of $38.80 per hour throughout the discussion in this section of this rule for the Hospital IQR Program.

b. Information Collection Burden Estimates for Proposed Policies Related to eCQM Reporting and Submission Requirements for the CY 2021 Reporting Period/FY 2023 Payment Determination, the CY 2022 Reporting Period/FY 2024 Payment Determination, and the CY 2023 Reporting Period/FY 2025 Payment Determination and Subsequent Years

In the FY 2020 IPPS/LTCH PPS final rule, we finalized eCQM reporting and submission requirements such that hospitals submit one, self-selected calendar quarter of data for four eCQMs for the CYs 2020 and 2021 reporting periods/FYs 2022 and 2023 payment determinations (84 FR 42503) and one, self-selected calendar quarter of data for three self-selected eCQMs and the Safe Use of Opioids—Concurrent Prescribing eCQM for the CY 2022 reporting period/FY 2024 payment determination (84 FR 42505). Our related information collection estimates were discussed at (84 FR 42604).

In sections VIII.A.10.e.(1). through (4). of the preamble to this proposed rule, we are proposing to progressively increase the number of quarters of eCQM data reported, from one self-selected quarter of data to four quarters of data over a 3-year period, by requiring hospitals to report: (1) Two quarters of data for the CY 2021 reporting period/FY 2023 payment determination, while continuing to require hospitals to report four self-selected eCQMs; (2) three quarters of data for the CY 2022 reporting period/FY 2024 payment determination, while continuing to report three self-selected eCQMs and the Safe Use of Opioids; and (3) four quarters of data beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years, while continuing to require hospitals to report three self-selected eCQMs and the Safe Use of Opioids—Concurrent Prescribing eCQM. We believe there would be a progressive increase to the burden estimate over the 3-year period due to these proposed policies.

We previously estimated the information collection burden associated with the eCQM reporting and submission requirements to be 40 minutes per hospital per year (10 minutes × 4 eCQMs × 1 quarter = 40 minutes), or 0.67 hours per hospital per year (40 minutes/60). We estimated a total annual burden of 2,200 hours across all IPPS hospitals (0.67 hours × 3,300 IPPS hospitals). Using the updated wage estimate as described previously, we estimate this to represent a total annual cost of $85,360 ($38.80 hourly wage × 2,200 annual hours) across all IPPS hospitals. Based on our proposal to progressively increase the number of quarters of data reported, from one self-selected quarter of data to four quarters of data over a 3-year period, we estimate an annual burden increase of 2,200 hours and $85,360 for all participating IPPS hospitals for each of the CY 2021 reporting period/FY 2023 payment determination, CY 2022 reporting period/FY 2024 payment determination, and CY 2023 reporting period/FY 2025 payment determination by increasing the number of quarters of eCQM data required to be reported by hospitals from one self-selected quarter of data to two quarters of data, then to three quarters of data, and finally to four quarters of data, respectively, for a total increase of 6,600 hours (2,200 hours + 2,200 hours + 2,200 hours) and $256,080 ($85,360 + $85,360 + $85,360) across a 3-year period for all participating IPPS hospitals.

c. Information Collection Burden Estimate for Proposed eCQM Public Display Requirements Beginning With the CY 2021 Reporting Period/FY 2023 Payment Determination

In section VIII.A.13.b. of the preamble to this proposed rule, we are proposing to begin public display of eCQM data beginning with data reported by hospitals for the CY 2021 reporting period and for subsequent years. Because hospitals would not have any additional information collection requirements, we believe there would be no change to the information collection burden estimate due to this policy, but

[515] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records and Health Information Technicians. Available at: *https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.*

acknowledge that there are other types of burden associated with this proposal. For example, there is burden associated with the optional reviewing of hospital-specific reports during the public reporting preview; however, we believe this burden is nominal because hospitals already review these reports with respect to other types of measures for the Hospital IQR Program.

d. Information Collection Burden Estimate for Proposed Updates to the Processes for Validation of Hospital IQR Program Measure Data

In section VIII.A.11. of the preamble to this proposed rule, we are proposing to make several changes to streamline the validation process. We are proposing to: (1) Require the use of electronic file submissions via a CMS-approved secure file transmission process and no longer allow the submission of paper copies of medical records or copies on digital portable media such as CD, DVD, or flash drive, beginning with validation of Q1 2021 data affecting the FY 2024 payment determination; (2) combine the validation processes for chart-abstracted measures and eCQMs by: (a) Aligning data submission quarters, with the validation quarters affecting the FY 2023 payment determination serving as a transition year before being fully aligned as to validation quarters affecting the FY 2024 payment determination; (b) combining hospital selection, including: (i) Reducing the pool of hospitals randomly selected for chart-abstracted measure validation, and (ii) integrating and applying targeting criteria for eCQM validation, beginning with validation affecting the FY 2024 payment determination; (c) removing previous exclusion criteria; and (d) combining scoring processes by providing one combined validation score for the validation of chart-abstracted measures and eCQMs with the eCQM portion of the combined score weighted at zero, beginning with validation affecting the FY 2024 payment determination; and (3) formalize the process for conducting educational reviews for eCQM validation in alignment with current processes for providing feedback for chart-abstracted validation results, beginning with eCQM validation affecting the FY 2023 payment determination.

As noted in the FY 2017 IPPS/LTCH IPPS final rule (81 FR 57261), 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 CD–ROMs, DVDs, 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. In addition, in the FY 2017 IPPS/LTCH IPPS final rule (81 FR 57261), we finalized that for eCQM validation, we reimburse hospitals at $3.00 per record for providing medical records as electronic files submitted via secure file transmission (paper copies and digital portable media are not accepted for eCQM validation). Because we directly reimburse, we do not anticipate any net change in information collection burden associated with our 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.

We do not anticipate any net change in information collection burden associated with our proposals to align the data submission quarters, to combine the hospital selection process by reducing the pool of hospitals randomly selected for validation for chart-abstracted measures from 400 hospitals to up to 200 hospitals, or to combine the scoring processes to provide one combined validation score for the validation of chart-abstracted measures and eCQMs. However, we refer readers to section I.K. of Appendix A of this proposed rule for a discussion of the potential burden reduction other than information collection burden that we believe hospitals could experience that are associated with our proposals to align the validation processes for chart-abstracted measures and eCQMs. In addition, we do not anticipate any information collection burden associated with our proposal to formalize the process for conducting educational reviews for eCQM validation. As discussed in section VIII.A.11.b.(3). of the preamble to this proposed rule, this process would allow any validated hospital to request an educational review of their eCQM validation results with CMS.

We previously estimated the information collection burden associated with eCQM validation to be 80 minutes per record, or approximately 11 hours per hospital per year (80 minutes per record × 8 records × 1 quarter/60 = 10.67 hours) (81 FR 57261). We estimated a total annual burden of approximately 2,200 hours across 200 IPPS hospitals selected for eCQM validation each year (11 hours × 200 IPPS hospitals). Using the updated wage estimate as described previously, we estimate this to represent a total annual cost of $85,360 (2,200 hours × $38.80) across 200 hospitals.

The previous estimate of 80 minutes per record was based on our limited experience working with voluntary hospital participants during the eCQM validation pilot conducted in 2015 (79 FR 50269 through 50272). For the validation pilot, participating hospitals attended a 30-minute pre-briefing session and had to install CMS-approved software that allowed our Clinical Data Abstraction Center (CDAC) contractor to remotely view isolated records in real-time under hospital supervision in order to compare all abstracted data with QRDA Category I file data and summarize the results of the real-time session (79 FR 50270). Since this 2015 pilot, the eCQM validation process that we have implemented under the Hospital IQR Program has been significantly streamlined so that we no longer need hospitals to allow remote access to the CDAC contractor to view records in real-time under each hospital's supervision nor for them to engage in discussions with our contractor during the process. Instead, hospitals selected for eCQM validation are required to submit timely and complete copies of medical records on eCQMs selected for validation to CMS by submitting records in PDF file format within 30 calendar days following the medical records request date listed on the CDAC request form via the QualityNet secure file transmission process (81 FR 57179).

Based on this updated process, as well as hospitals having gained several years of experience using EHRs, we are revising our previous estimate from 80 minutes per record to 10 minutes per record. This is the amount of time we estimate is needed for hospitals to create PDF files and to electronically submit each medical record to us via the CMS-approved secure file transmission process. The estimate of 10 minutes per record is similar to our estimate of 10 minutes per eCQM per quarter in submitting QRDA Category I files via the QualityNet secure portal (81 FR 57260). We note that as mentioned previously, hospitals will still be reimbursed at $3.00 per record (81 FR 57261).

In addition, we anticipate that our proposal to progressively increase the number of quarters of eCQM data reported, from one self-selected quarter of data to four quarters of data over a 3-year period, would similarly increase the total number of quarters of data from which cases would be selected for

eCQM validation over a 3-year period. We also anticipate that our proposal to combine the hospital selection process such that the Hospital IQR Program would validate a pool of up to 400 hospitals across measure types (up to 200 hospitals would be randomly selected and up to 200 hospitals would be selected using targeting criteria) would increase the number of hospitals selected for eCQM validation from up to 200 hospitals to up to 400 hospitals. Therefore, we estimate the following burden changes over a 3-year period using the revised estimate of 10 minutes (0.1667 hours) per record as discussed previously. For eCQM validation of CY 2021 data affecting the FY 2024 payment determination, we estimate a total burden of 1,067 hours across 400 IPPS hospitals selected for eCQM validation (0.1667 hours × 2 quarters × 8 cases × 400 IPPS hospitals) and $41,400 (1,067 hours × 38.80). This reflects a total burden decrease of 1,133 hours (2,200 hours − 1,067 hours) and $43,960 ($85,360 − $41,400) compared to our previous burden estimate for eCQM validation affecting the FY 2024 payment determination. For eCQM validation of CY 2022 data affecting the FY 2025 payment determination, we estimate a total burden of 1,600 hours across 400 IPPS hospitals selected for eCQM validation (0.1667 hours × 3 quarters × 8 cases × 400 IPPS hospitals) and $62,080 (1,600 hours × $38.80). This reflects a total burden decrease of 600 hours (2,200 hours − 1,600 hours) and $23,280 ($85,360 − $62,080) compared to our previous burden estimate for eCQM validation affecting the FY 2025 payment determination. For eCQM validation of CY 2023 data affecting the FY 2026 payment determination, and for subsequent years, we estimate a total burden of 2,133 hours across 400 IPPS hospitals selected for eCQM validation (0.1667 hours × 4 quarters × 8 cases × 400 IPPS hospitals) and $82,760 (2,133 hours × $38.80). This reflects a total burden decrease of 67 hours (2,200 hours − 2,133 hours) and $2,600 ($85,360 − $82,760) compared to our previous burden estimate for eCQM validation affecting the FY 2026 payment determination and subsequent years.

e. Summary of Information Collection Burden Estimates for the Hospital IQR Program

In summary, under OMB control number 0938–1022, we estimate a total information collection burden increase for 3,300 IPPS hospitals of 6,533 hours (6,600 hours − 67 hours) associated with our proposed policies and updated burden estimates described previously and a total cost increase related to this information collection of approximately $253,480 (6,533 hours × $38.80) (which also reflects use of an updated hourly wage rate as previously discussed), across a 4-year period from the CY 2021 reporting period/FY 2023 payment determination through the CY 2024 reporting period/FY 2026 payment determination, compared to our currently approved information collection burden estimates. The tables summarize the total burden changes for each respective FY payment determination compared to our currently approved information collection burden estimates (the table for the FY 2026 payment determination reflects the cumulative burden changes). We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1022.

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Summary of Hospital IQR Program Information Collection Burden Change for the CY 2021 Reporting Period/FY 2023 Payment Determination

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the FY 2023 Payment Determination								
Activity	**Estimated Time per Record (in minutes)**	**Number Reporting Quarters per Year**	**Number of IPPS Hospitals Reporting**	**Average Number of Records per Hospital per Quarter**	**Annual Burden (hours) per Hospital**	**Proposed Annual Burden (hours) Across IPPS Hospitals**	**Previously Finalized Annual Burden (hours) Across IPPS Hospitals**	**Net Difference in Annual Burden Hours**
Increase Quarters of eCQM Data from 1 to 2 Quarters for 4 eCQMs	40	2	3,300	N/A	1.33	4,400	2,200	2,200
	Total Change in Information Collection Burden Hours: 2,200							
	Total Cost Estimate: Updated Hourly Wage ($38.80) x Change in Burden Hours (2,200) = **$85,360**							

Summary of Hospital IQR Program Information Collection Burden Change for the CY 2022 Reporting Period/FY 2024 Payment Determination

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the FY 2024 Payment Determination							
Activity	**Estimated Time per Record (in minutes)**	**Number Reporting Quarters per Year**	**Number of IPPS Hospitals Reporting**	**Average Number of Records per Hospital per Quarter**	**Annual Burden (hours) per Hospital**	**Proposed Annual Burden (hours) Across IPPS Hospitals**	**Previously Finalized Annual Burden (hours) Across IPPS Hospitals**	**Net Difference in Annual Burden Hours**
Increase Quarters of eCQM Data from 1 to 3 Quarters for 4 eCQMs	40	3	3,300	N/A	2	6,600	2,200	4,400
Increase Number of Hospitals Selected for eCQM Validation and Quarters of Data Validated from 1 to 2 Quarters	10*	2	400	8	2.67	1,067	2,200	-1,133
	Total Change in Information Collection Burden Hours: 3,267							
	Total Cost Estimate: Updated Hourly Wage ($38.80) x Change in Burden Hours (3,267) = **$126,760**							

*Reflects revised estimate from 80 minutes per record to 10 minutes per record as discussed previously.

Summary of Hospital IQR Program Information Collection Burden Change for the CY 2023 Reporting Period/FY 2025 Payment Determination

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the FY 2025 Payment Determination							
Activity	**Estimated Time per Record (in minutes)**	**Number Reporting Quarters per Year**	**Number of IPPS Hospitals Reporting**	**Average Number of Records per Hospital per Quarter**	**Annual Burden (hours) per Hospital**	**Proposed Annual Burden (hours) Across IPPS Hospitals**	**Previously Finalized Annual Burden (hours) Across IPPS Hospitals**	**Net Difference in Annual Burden Hours**
Increase Quarters of eCQM Data from 1 to 4 Quarters for 4 eCQMs	40	4	3,300	N/A	2.67	8,800	2,200	6,600
Increase Number of Hospitals Selected for eCQM Validation and Quarters of Data Validated from 1 to 3 Quarters	10*	3	400	8	4	1,600	2,200	-600
	Total Change in Information Collection Burden Hours: 6,000							
	Total Cost Estimate: Updated Hourly Wage ($38.80) x Change in Burden Hours (6,000) = **$232,800**							

*Reflects revised estimate from 80 minutes per record to 10 minutes per record as discussed previously.

Summary of Hospital IQR Program Information Collection Burden Change for the CY 2024 Reporting Period/FY 2026 Payment Determination

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the FY 2026 Payment Determination							
Activity	**Estimated Time per Record (in minutes)**	**Number Reporting Quarters per Year**	**Number of IPPS Hospitals Reporting**	**Average Number of Records per Hospital per Quarter**	**Annual Burden (hours) per Hospital**	**Proposed Annual Burden (hours) Across IPPS Hospitals**	**Previously Finalized Annual Burden (hours) Across IPPS Hospitals**	**Net Difference in Annual Burden Hours**
Increase Quarters of eCQM Data from 1 to 4 Quarters for 4 eCQMs	40	4	3,300	N/A	2.67	8,800	2,200	6,600
Increase Number of Hospitals Selected for eCQM Validation and Quarters of Data Validated from 1 to 4 Quarters	10*	4	400	8	5.33	2,133	2,200	-67
	Total Change in Information Collection Burden Hours: 6,533							
	Total Cost Estimate: Updated Hourly Wage ($38.80) x Change in Burden Hours (6,533) = **$253,480**							

*Reflects revised estimate from 80 minutes per record to 10 minutes per record as discussed previously.

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8. ICRs for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

As discussed in section VIII.B. of the preamble of this proposed rule, section 1866(k)(1) of the Act requires, for purposes of FY 2014 and each subsequent fiscal year, that a hospital described in section 1886(d)(1)(B)(v) of the Act (a PPS-exempt cancer hospital, or a PCH) submit data in accordance with section 1866(k)(2) of the Act with respect to such fiscal year. There is no financial impact to PCH Medicare payment if a PCH does not participate.

As discussed in section VIII.B.3. of the preamble of this proposed rule, we are proposing to adopt refined versions of two existing measures: Catheter-associated Urinary Tract Infection (CAUTI) and Central Line-associated Bloodstream Infection (CLABSI), beginning with the FY 2023 program year. The refined versions of the measure incorporate an updated SIR calculation methodology developed by the Centers for Disease Control and Prevention (CDC) that calculates rates stratified by patient care locations within PCHs, without the use of predictive models or comparisons in the rate calculations. If our proposal is finalized as proposed, we do not estimate any net change in burden hours for the PCHQR Program for the FY 2023 program year because there would be no change in the data submission requirements for PCHs. We note that burden estimates for these CDC NHSN measures are submitted separately under OMB control number 0920–0666.

The PCHQR Program measure set would continue to consist of 15 measures for the FY 2023 program year. As previously stated, the most recent data from the Bureau of Labor Statistics reflects a median hourly wage of $19.40 (previously $18.83). Consequently, while our proposal will not yield a net change in burden hours, the change in labor wage will cause an increase in burden cost for the PCHQR Program. Therefore, using the previously finalized hourly burden estimate of 75,779 burden hours across the 11 PCHs for data collection and submission of all 15 measures, we estimate a total annual labor cost of $2,940,225 (75,779 hours × $38.80 per hour) for all 11 PCHs for the FY 2023 program year. The burden hours associated with these reporting requirements is currently approved under OMB control number 0938–1175. The updated burden cost, based on the increase in the labor wage, will be revised and submitted to OMB.

9. ICRs for the Promoting Interoperability Programs

In section VIII.D. of the preamble of this proposed rule, we discuss several proposals for the Medicare and Medicaid Promoting Interoperability Programs. OMB has currently approved 623,562 total burden hours and approximately $61 million under OMB control number 0938–1278, accounting for information collection burden experienced by approximately 3,300 eligible hospitals and CAHs (Medicare-only and dual-eligible) that attest to CMS under the Medicare Promoting Interoperability Program. The collection of information burden analysis in this proposed rule focuses on eligible hospitals and CAHs that attest to the objectives and measures, and report CQMs, under the Medicare Promoting Interoperability Program for the reporting period in CY 2021.

b. Summary of Policies for Eligible Hospitals and CAHs That Attest to CMS Under the Medicare Promoting Interoperability Program

In section VIII.D.3.b. of the preamble of this rule, we are proposing the following changes for eligible hospitals and CAHs that attest to CMS under the Medicare Promoting Interoperability Program: (1) An EHR reporting period of a minimum of any continuous 90-day period in CY 2022 for new and returning participants (eligible hospitals and CAHs); (2) to maintain the Electronic Prescribing Objective's Query of PDMP measure as optional and worth 5 bonus points in CY 2021; (3) to modify the name of the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure; (4) to progressively increase the number of quarters for which hospitals are required to report eCQM data, from the current requirement of one self-selected calendar quarter of data, to four calendar quarters of data, over a 3-year period. Specifically, we propose to require: (a) 2 Self-selected calendar quarters of data for the CY 2021 reporting period; (b) 3 self-selected calendar quarters of data for the CY 2022 reporting period; and (c) 4 self-selected calendar quarters of data beginning with the CY 2023 reporting period, where the proposed submission period for the Medicare Promoting Interoperability Program would be the 2 months following the close of the CY 2023 (ending February 28, 2024); (5) to begin publicly reporting eCQM performance data beginning with the eCQM data reported by eligible hospitals and CAHs for the reporting period in CY 2021 on the *Hospital Compare* and/or *data.medicare.gov* websites or successor websites; (6) to correct errors and amend regulation text under § 495.104(c)(5)(viii)(B) through (D) regarding transition factors under section 1886(n)(2)(E)(i) of the Act for the incentive payments for Puerto Rico eligible hospitals; and (7) to correct errors and amend regulation text under § 495.20(e)(5)(iii) and (l)(11)(ii)(C)(*1*) for regulatory citations for the ONC certification criteria. We are amending our regulation texts as necessary to incorporate these proposed changes.

c. Summary of Collection of Information Burden Estimates

(1) Summary of Estimates Used To Calculate the Collection of Information Burden

In the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017 final rule (80 FR 62917), we estimated it will take an individual provider or designee approximately 10 minutes to attest to each objective and associated measure that requires a numerator and denominator to be generated. The measures that require a ''yes/no'' response will take approximately one minute to complete. We estimated that the Security Risk Analysis measure will take approximately 6 hours for an individual provider or designee to complete (we note this measure is still part of the program, but is not subject to performance-based scoring). We continue to believe these are appropriate burden estimates for reporting and have used this methodology in our collection of information burden estimates for this proposed rule.

Given the proposals, we estimate a total burden estimate of 6 hours 31 minutes per respondent (6.5 hours) which remains unchanged from the FY 2020 IPPS/LTCH PPS final rule (84 FR 42044).

Medicare Promoting Interoperability Program Estimated Annual Information Collection Burden Per Respondent for CY 2021: § 495.24(e) - Objectives/Measures Medicare (Eligible Hospitals/CAHs)

Objective	Measure	Burden Estimate per Eligible Hospital and CAH
N/A	Security Risk Analysis	6 hours
Electronic Prescribing	e-Prescribing	10 minutes
	Query of PDMP	
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	10 minutes
	Support Electronic Referral Loops by Receiving and Incorporating Health	
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	10 minutes
Public Health and Clinical Data Exchange	• Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Public Health Registry Reporting • Clinical Data Registry -Reporting • Electronic Reportable Laboratory Result Reporting	1 minute
Total Burden Estimate per Respondent		6 hours 31 minutes (6.5 hours)

(2) Hourly Labor Costs

In the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017 final rule (80 FR 62917), we estimated a mean hourly rate of $63.46 for the staff involved in attesting to EHR technology, meaningful use objectives and associated measures, and electronically submitting the clinical quality measures. We had previously used the mean hourly rate of $68.22 for the necessary staff involved in attesting to the objectives and measures under 42 CFR 495.24(e) in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42609), however, this rate has since been updated to $69.34 for the FY 2021 proposed rule based upon recently-released 2018 data from the Bureau of Labor Statistics (BLS).[516]

In summary, if our proposal is finalized as proposed, we do not estimate any net change in burden hours for the Medicare Promoting Interoperability Program for CY 2021, as there is no substantive change in measures or data submission requirements for eligible hospitals and CAHs in our proposals. However, we discovered an incorrect mathematical calculation in last year's final rule and are correcting it in the table that follows. The correction we are providing in following table is that 3,300 responses multiplied by 6.5 burden hours equals 21,450 total annual burden hours (a decrease in 44 hours from what was mistakenly reported last year). While we reiterate that the proposals included in this rule do not contribute to additional or reduced burden hours, please note that the correction of this error will update subsequent burden calculations detailed below.

As previously stated, recent data from the BLS reflects a median hourly staff wage of $69.34 (previously $68.22). Consequently, while our proposal will not yield a net change in burden hours, the change in labor wage will cause an increase in burden cost for the program. Therefore, using the updated estimate of total annual burden hours of 21,450 burden hours across 3,300 responses to data collection and submissions for the program objectives' measures, we estimate a total annual labor cost of $1,487,343 (21,450 hours × $69.34 per hour) for the CY 2021 EHR reporting period. The burden hours associated with these reporting requirements is currently approved under OMB control number 0938–1278. The updated burden cost, based solely on the increase in labor wages, will be revised and submitted to OMB.

Medicare Promoting Interoperability Program Estimated Annual Information Collection Burden (Total Cost) for CY 2021

Regulations Section	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Cost ($)
§495.24(e)	3,300	3,300	6.5	21,450	69.34	1,487,343

[516] *https://www.bls.gov/oes/current/oes231011.htm.*

As no measures have been removed nor introduced since last year's final rule, but are mainly continuations of current policies, we do not consider the proposals included in this section to change the program. That being said, the numerical-correction of the total annual burden hours and an updated BLS hourly labor cost of reporting will impact the program's total cost. Thus, the Collection Burden's Total Cost for CY 2021 of $1,487,343 is an increase of $21,022.32 from last year's final rule.

10. ICR for the Submission of Electronic Medical Records to Quality Improvement Organizations (QIOs)

In section IX.A. of this proposed rule, we discuss our proposals relating to the submission of patient records to the QIOs in an electronic format by providers and practitioners in accordance with § 476.78 and by institutions and practitioners in accordance with § 480.111. These patient records must be submitted to the QIOs for purposes of one or more QIO functions. As a result, the collection and review of such records by the QIOs constitutes an audit, investigation or administrative action as specified in section 1154(a) of the Act. Therefore, we believe these collection requirements are not subject to the PRA as stipulated under 5 CFR 1320.4(a)(2).

11. ICR for Payer-Specific Negotiated Charges Data Collection

Section IV.P. of the preamble of this proposed rule discusses the proposed data collection of market-based payment rate information by MS–DRG on the Medicare cost report for cost reporting periods ending on or after January 1, 2021. First, hospitals would report the median payer-specific negotiated charge by MS–DRG for payers that are MA organizations. Second, hospitals would report the median payer-specific negotiated charge by MS–DRG for all third-party payers, which include MA organizations. We propose to collect this market-based information on new form CMS–2552–10, Worksheet S–12.

Consistent with the desire to reduce the Medicare program's reliance on the hospital chargemaster, as well as to inject market pricing into Medicare FFS reimbursement, thereby addressing the objectives under E.O.s 13813 and 13890, we believe reporting this market based information will be less burdensome for hospitals given that hospitals are required, beginning in CY 2021, to make public their payer-specific negotiated charges for the same service packages under the requirements we finalized in the Hospital Price Transparency final rule. The market-based rate information we are proposing to collect on the Medicare cost report would be the median of the payer-specific negotiated charges for every MS–DRG, that the hospital has negotiated with its MA organizations and all of its third party payers, which include MA organizations. We believe that because hospitals are already required to publically report the payer-specific negotiated charge information that they will use to calculate these medians, the additional calculation and reporting of the median payer-specific negotiated charge will be less burdensome for hospitals.

Burden hours estimate the time (number of hours) required for each IPPS hospital to complete ongoing data gathering and recordkeeping tasks, search existing data resources, review instructions, and complete the Form CMS–2552–10, Worksheet S–12. The most recent data from the System for Tracking Audit and Reimbursement, an internal CMS data system maintained by the Office of Financial Management (OFM), reports that 3,189 hospitals, the current number of Medicare certified IPPS hospitals, file Form CMS–2552–10 annually.

In section IV.P.2.c. of the preamble to this proposed rule, we proposed that subsection (d) hospitals in the 50 states and DC, as defined at section 1886(d)(1)(B) of the Act, and subsection (d) Puerto Rico hospitals, as defined under section 1886(d)(9)(A) of the Act, would be required to report the median payer-specific negotiated charge information. Hospitals that do not negotiate payment rates and only receive non-negotiated payments for service would be exempted from this definition. We recognize that Critical Access Hospitals (CAHs) may, in some instances, negotiate payment rates; however, because CAHs are not subsection (d) hospitals and are not paid on the basis of MS–DRGs, CAHs would be excluded from this proposed requirement. We also are proposing that hospitals in Maryland, which are currently paid under the Maryland Total Cost of Care Model, would be exempt from this data collection requirement during the performance period of the Model. Based on this proposal, we estimate that 3,189 hospitals would be required to comply with this market-based data collection proposal.

Based on our understanding of the resources necessary to report this information, we estimate an average annual burden per hospital of 15 hours (5 hours for recordkeeping and 10 hours for reporting) for the Worksheet S–12. The burden is minimized because the median payer-specific negotiated charge data collected on the Worksheet S–12 is based on payer-specific data maintained by the hospital.

We estimated the total annual burden hours as follows: 3,189 hospitals times 15 hours per hospital equals 47,835 annual burden hours.

The 5 hours for recordkeeping include hours for bookkeeping, accounting and auditing clerks; the 10 hours for reporting include accounting and audit professionals' activities. We believe the basic median calculation would be captured within the recordkeeping portion of this assessment.

Based on the most recent Bureau of Labor Statistics (BLS) in its 2019 Occupation Outlook Handbook, the mean hourly wage for Category 43–3031 (bookkeeping, accounting and auditing clerks) is $20.65 (*https://www.bls.gov/oes/current/oes433031.htm*). We added 100 percent of the mean hourly wage to account for fringe and overhead benefits, which calculates to $41.30 ($20.65 + $20.65) and multiplied it by 5 hours, to determine the annual recordkeeping costs per hospital to be $206.50 ($41.30 × 5 hours).

The mean hourly wage for Category 13–2011 (accounting and audit professionals) is $38.23 (*www.bls.gov/oes/current/oes132011.htm*). We added 100 percent of the mean hourly wage to account for fringe and overhead benefits, which calculates to $76.46 ($38.23 + $38.23) and multiplied it by 10 hours, to determine the annual reporting costs per hospital to be $764.60 ($76.46 × 10 hours). We have calculated the total annual cost per hospital of $971.10 by adding the recordkeeping costs of $206.50 plus the reporting costs of $764.60 (see Table K1). We estimated the total annual cost to be $3,096,838 ($971.10 times 3,189 IPPS hospitals) (see Table K2).

Table K1: Estimated Annual Cost per Hospital

Average Hourly Rate Analysis: April 2020	Hours Per Response	BLS Cost Per Hour	Cost Per Hour with Overhead and Fringes	Cost Per Response	Average Hourly Rate
Reporting	10	38.23	76.46	764.60	
Record Keeping	5	20.65	41.30	206.50	
Third Party Disclosure					
Total	15			971.10	N/A

Table K2: Estimated Total Annual Cost

	Currently Approved			Total Requested			Increase/(Decrease) Over Currently Approved	
Respondent Costs	Number of Providers	Per Provider	Total Hours	Number of Providers	Per Provider	Total Hours	Number of Providers	Total Hours
Hours required for CR preparation	3,189	-	-	3,189	15	47,835	-	47,835
Cost for CR preparation						$3,096,838		$3,096,838

We believe that because hospitals are already required to publically report the payer-specific negotiated charge information that they will use to calculate these medians, the additional calculation and reporting of the median payer-specific negotiated charge will be less burdensome for hospitals than if hospitals did not already have this information compiled. The Hospital Price Transparency final rule required that hospitals establish, update, and make public via the internet standard charges in two different ways: (1) A single machine-readable file with a list of standard charges (including gross charges, payer-specific negotiated charges, de-identified minimum negotiated charges, de-identified maximum negotiated charges, and discounted cash prices) for all items and services including service packages identified by MS–DRG; and (2) standard charges (including payer-specific negotiated charges, discounted cash prices, de-identified minimum negotiated charges, de-identified maximum negotiated charges) in a consumer-friendly manner 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. We note that the proposed data collection requirement in this proposed rule would apply to a smaller subset of hospitals as compared to the public reporting requirements under the Hospital Price Transparency final rule.

In total, the Hospital Price Transparency final rule estimated in the first year of public reporting, it would take a hospital an estimated 150 hours at a cost of $11,898.60 per hospital [517] to implement and comply with the requirements, as specified at 45 CFR part 180. The estimated 150 hours of burden for the first year includes 10 total hours for a lawyer ($138.68/hour) and general operations manager ($119.12/hour) to read and review the rule; 80 hours for a business operations specialist ($74.00/hour) to gather and compile the required information and post it in the form and manner specified in the Hospital Price Transparency final rule; 30 hours for a network and computer system administrator ($83.72/hour) to comply with the form and manner standards set forth in the Hospital Price Transparency final rule; 30 hours for a registered nurse ($72.60/hour) to capture the necessary clinical input to comply with reporting the CMS-specified and hospital-selected shoppable services. (150 hours = 5 hours + 5 hours + 80 hours + 30 hours + 30 hours; totaling a cost of $11,898.60 ($693.40 + $595.60 + $5,920 + $2,511.60 + $2,178) per hospital.)

In this proposed rule, we propose that hospitals calculate and report on the Medicare cost report two median payer-specific negotiated charges using the payer-specific negotiated charge data they are required to make public under the Hospital Price Transparency final rule. Therefore, the burden associated with establishing and updating the payer-specific negotiated charges has already been assumed. Specifically, given that the payer-specific negotiated charge is one of the five types of standard charges (gross charges, payer-specific negotiated charges, de-identified minimum negotiated charges, de-identified maximum negotiated charges, and discounted cash prices) that the Hospital Price Transparency final rule requires that hospitals estimate, update and make public, we believe that a fraction of the estimated 80 hours of burden associated with gathering, compiling, and posting, that required information in the form and manner specified in the Hospital Price Transparency final rule, would support the reporting efforts in this proposed rule. We are interested in hearing from

[517] The estimated hourly cost for each labor category used in this analysis were referencing the Bureau of Labor Statistics report on Occupational Employment and Wages, May 2018 (Bureau of Labor Statistics report on Occupational Employment and Wages, May 2018 Available at: *https://www.bls.gov/oes/2018/may/oes_nat.htm*). We also have calculated the cost of overhead at 100 percent of the mean hourly wage, in line with the Hospital Inpatient and Hospital Outpatient Quality Reporting programs (81 FR 57260 and 82 FR 59477, respectively).

commenters if burden estimates in this proposed rule accurately capture the time needed to take information already gathered for the Hospital Price Transparency final rule and report it to CMS in the manner requested.

We refer readers to the Hospital Price Transparency final rule for the full burden assessment analysis for the requirements set forth within that final rule (84 FR 65524).

We maintain that the estimated burden associated with completing the Worksheet S–12 would be 15 hours (5 hours for recordkeeping and 10 hours for reporting), given the minimized burden since hospitals would already have collected the payer-specific negotiated charge data and would only then need to calculate the median payer-specific negotiated charge by MS–DRG for payers that are MA organizations and for all third-party payers.

Further instructions for the reporting of this market-based data collection proposal on the Medicare cost report will be discussed in a forthcoming revision of the ICR request currently approved under OMB control number 0938–0050, expiration date March 31, 2022.

12. Summary of All Burden in This Proposed Rule

The following chart reflects the total burden and associated costs for the provisions included in this proposed rule.

Information Collection Requests	Burden Hours Increase/Decrease (+/-)*	Cost (+/-)*
Hospital Inpatient Quality Reporting Program	+6,533	+$253,480
Hospital Value-Based Purchasing Program[1]	N/A	N/A
Hospital-Acquired Condition Reduction Program	-14,400	-$558,720
Hospital Readmissions Reduction Program[2]	N/A	N/A
Promoting Interoperability Programs	-44	+$24,024
PPS-Exempt Cancer Hospital Quality Reporting Program[3]	N/A	+$86,388
Payer-Specific Negotiated Charges Data Collection	+47,835	+$3,096,838
TOTAL	**39,924**	**$2,902,010**

* Numbers rounded.

[1] Because the FY 2023 Hospital VBP Program will use data that are also used to calculate quality measures in other programs and Medicare fee-for-service claims data that hospitals are already submitting to CMS for payment purposes, the program does not anticipate any change in burden associated with this proposed rule.

[2] Because the Hospital Readmissions Reduction Program measures are all collected via Medicare fee-for service- claims that hospitals are already submitting to CMS for payment purposes, there is no unique information collection burden associated with the program.

[3] The increase in cost is a function of the Bureau of Labor Statistics' updated labor wage.

C. 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 proposed rule, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

D. Waiver of the 60-Day Delayed Effective Date for the Final Rule

We are committed to ensuring that we fulfill our statutory obligation to update the IPPS and LTCH PPS as required by law and are working diligently in that regard. We ordinarily provide a 60-day delay in the effective date of final rules after the date they are issued in accord with the Congressional Review Act (CRA) (5 U.S.C. 801(a)(3)). However, section 808(2) of the CRA provides that, if an agency finds good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the rule shall take effect at such time as the agency determines.

The United States is responding to an outbreak of respiratory disease caused by a novel (new) coronavirus that has now been detected in more than 190 locations internationally, including in all 50 States and the District of Columbia. The virus has been named ''SARS-CoV–2'' and the disease it causes has been named ''coronavirus disease 2019'' (abbreviated ''COVID–19'').

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a ''Public Health Emergency of international concern'' (PHEIC). On January 31, 2020, Health and Human Services Secretary, Alex M. Azar II, declared a PHE for the United States to aid the nation's healthcare community in responding to COVID–19. On March 11, 2020, the WHO publicly characterized COVID–19 as a pandemic. On March 13, 2020 the President of the United States declared the COVID–19 outbreak a national emergency.

Due to CMS prioritizing efforts in support of containing and combatting the COVID–19 PHE, and devoting significant resources to that end, the work needed on the IPPS and LTCH PPS payment rule will not be completed in accordance with our usual schedule for this rulemaking, which aims for a publication date of at least 60 days before the start of the fiscal year to which it applies. Up to an additional 30 days may be needed to complete the work needed on this payment rule. The IPPS and LTCH PPS payment rule is necessary to annually review and update the payment systems, and it is critical to ensure that the payment policies for these systems are effective on the first day of the fiscal year to which they are intended to apply. Therefore, due to CMS prioritizing efforts in support of containing and combatting the COVID–19 PHE, and devoting significant resources to that end, we are hereby waiving the 60-day delay in the effective date of the IPPS and LTCH PPS final rule; it would be contrary to the public interest for CMS to do otherwise. However, we do expect

to provide a 30-day delay in the effective date of the final rule in accord with section 5 U.S.C. 553(d) of the Administrative Procedure Act, which ordinarily requires a 30-day delay in the effective date of a final rule from the date of its public availability in the **Federal Register**, and section 1871(e)(1)(B)(i) of the Act, which generally prohibits a substantive rule from taking effect before the end of the 30-day period beginning on the date of its public availability.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 417

Administrative practice and procedure, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs—health, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 476

Grant programs—health, Health care, Health facilities, Health professions, Quality Improvement Organizations (QIOs), Reporting and recordkeeping requirements.

42 CFR Part 480

Health care, Health professions, Health records, Penalties, Privacy, Quality Improvement Organizations (QIOs), Reporting and recordkeeping requirements.

42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Health professions, Health records, Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services proposed to amend 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

■ 2. Section 405.1801 is amended—
■ a. In paragraph (a), in the definition of ''Date of receipt''—
■ i. By revising paragraphs (1)(ii) and (2) introductory text;
■ ii. In paragraph (2)(i) by removing the phrase ''; or'' and adding a period in its place; and
■ iii. By adding paragraph (2)(iii); and
■ b. By revising paragraph (d) introductory text.

The revisions and addition read as follows:

§ 405.1801 Introduction.

(a) * * *

Date of receipt * * *

(1) * * *

(ii) For purposes of a contractor hearing, if no contractor hearing officer is appointed (or none is currently presiding), the date of receipt of materials sent to the contractor hearing officer (as permitted under paragraph (d) of this section) is presumed to be, as applicable, the date that the contractor stamps ''Received'' on the materials, or the date of electronic delivery.

* * * * *

(2) *A reviewing entity.* For purposes of this definition, a reviewing entity is deemed to include the Office of the Attorney Advisor. The determination as to the date of receipt by the reviewing entity to which the document or other material was submitted (as permitted under paragraph (d) of this section) is final and binding as to all parties to the appeal. The date of receipt of documents by a reviewing entity is presumed to be, as applicable, one of the following dates:

* * * * *

(iii) Of electronic delivery. *In writing* or *written* means a hard copy or electronic submission (subject to the restrictions in paragraph (d) of this section), as applicable throughout this subpart.

* * * * *

(d) *Method for submissions and calculating time periods and deadlines.* Except for subpoena requests being sent to a nonparty under § 405.1857(c), the reviewing entity may prescribe the method(s) by which a party must make a submission, including the requirement to use an electronic filing system for submission of documents. Such methods or instructions apply to any period of time or deadline prescribed or allowed under this subpart (for example, requests for appeal under §§ 405.1811(b), 405.1835(b), and 405.1837(c) and (e)) or authorized by a reviewing entity. In computing any period of time or deadline prescribed or allowed under this subpart or authorized by a reviewing entity the following principles are applicable:

* * * * *

§ 405.1811 [Amended]

■ 3. Section 405.1811 is amended in paragraph (c)(1) by removing the phrase ''the date the contractor stamped'' and adding in its place is the phrase ''the date of electronic delivery, or the date the contractor stamped''.

§ 405.1813 [Amended]

■ 4. Section 405.1813 is amended—
■ a. In paragraph (d) by removing the phrase ''must give prompt written notice to the provider, and mail a copy'' and adding in its place is the phrase ''must send prompt written notice to the provider, and send a copy''; and
■ b. In paragraph (e)(1) by removing the phrase ''promptly mails the decision'' and adding in its place is the phrase ''promptly sends the decision''.

§ 405.1814 [Amended]

■ 5. Section 405.1814 is amended in paragraph (c)(2) by removing the phrase ''must be mailed promptly'' and adding in its place is the phrase ''must be sent promptly''.

§ 405.1819 [Amended]

■ 6. Section 405.1819 is amended by removing the phrase ''prior to the mailing of notice'' and adding in its place is the phrase ''prior to the sending of notice''.

§ 405.1821 [Amended]

■ 7. Section 405.1821 is amended—
■ a. In paragraph (c)(1) by removing the phrase ''be mailed promptly'' and adding in its place is the phrase ''be sent promptly''; and
■ b. In paragraph (c)(3)(iii)(B) by removing the phrase ''Issue and mail'' and adding in its place is the phrase ''Issue and send''.

§ 405.1831 [Amended]

■ 8. Section 405.1831 is amended in paragraph (d) by removing the phrase ''must be mailed'' and adding in its place is the phrase ''must be sent''.

§ 405.1834 [Amended]

■ 9. Section 405.1834 is amended in paragraph (e)(3) by removing the phrase ''must be mailed'' and adding in its place is the phrase ''must be sent''.

§ 405.1835 [Amended]

■ 10. Section 405.1835 is amended—

■ a. In paragraph (b) introductory text by removing ''in writing to the Board'', ''(b)(1) through (b)(4)'', and ''(b)(1), (b)(2), or (b)(3)'' and adding in their places ''in writing in the manner prescribed by the Board'', ''(b)(1) through (4)'', and ''(b)(1), (2), or (3)'', respectively.

■ b. In paragraph (d) introductory text by removing removing ''in writing to the Board'', ''(d)(1) through (d)(4)'', and ''(d)(1), (d)(2), or (d)(3)'' and adding in their places ''in writing in the manner prescribed by the Board'', ''(d)(1) through (4)'', and ''(d)(1), (2), or (3)'', respectively.

§ 405.1836 [Amended]

■ 11. Section 405.1836 is amended —

■ a. In paragraph (d) by removing the phrase ''and mail a copy'' and adding in its place is the phrase ''and send a copy''; and

■ b. In paragraph (e)(1) by removing the phrase ''of this subpart'' wherever it appears and removing the phrase ''must be mailed'' and adding in its place is the phrase ''must be sent''.

§ 405.1840 [Amended]

■ 12. Section 405.1840 is amended paragraph (c)(2) by removing the phrase ''of this subpart'' wherever it appears and removing the phrase ''must be mailed'' and adding in its place is the phrase ''must be sent''.

■ 13. Section 405.1843 is amended—

■ a. By redesignating paragraph (a) as paragraph (a)(1);

■ b. In newly redesignated paragraph (a)(1) by removing the phrase ''of this subpart'';

■ c. By adding paragraph (a)(2); and

■ d. In paragraph (d)(2) by removing the phrase ''promptly mail copies'' and adding in its place is the phrase ''promptly send copies''.

The addition reads as follows:

§ 405.1843 Parties to proceedings in a Board appeal.

(a) * * *

(2) All parties to a Board appeal are to familiarize themselves with the instructions for handling a Provider Reimbursement Review Board (PRRB) appeal, including any and all requirements related to the electronic/online filing of documents.

* * * * *

§ 405.1845 [Amended]

■ 14. Section 405.1845 is amended in paragraph (h)(2)(iii) by removing the phrase ''Mail the remand'' and adding in its place is the phrase ''Send the remand''.

§ 405.1849 [Amended]

■ 15. Section 405.1849 is amended by removing the phrase ''mail written notice thereof to the parties at their last known addresses,'' and adding in its place is the phrase ''send notice thereof to the parties' contact information on file,''.

§ 405.1851 [Amended]

■ 16. Section 405.1851 is amended by removing the phrase ''mailing of notice'' and adding in its place is the phrase ''issuing of the notice''.

§ 405.1853 [Amended]

■ 17. Section 405.1853 is amended in paragraph (e)(5)(vi)(A) by removing the phrase ''issue and mail'' and adding in its place is the phrase ''issue and send''.

■ 18. Section 405.1857 is amended—

■ a. By revising paragraph (c)(1) introductory text; and

■ b. In paragraph (c)(4)(iii)(A) by removing the phrase ''mail promptly to each party'' and adding in its place is the phrase ''send promptly to each party''.

The revision reads as follows:

§ 405.1857 Subpoenas.

* * * * *

(c) * * *

(1) *Subpoena requests.* The requesting party must send any subpoena request submitted to the Board promptly to the party or nonparty subject to the subpoena, and to any other party to the Board appeal. If the subpoena request is being sent to a nonparty subject to the subpoena, then the subpoena request must be sent by certified mail. The request must—

* * * * *

§ 405.1868 [Amended]

■ 19. Section 405.1868 is amended in paragraph (d)(1) by removing the phrase ''must be mailed'' and adding in its place is the phrase ''must be sent''.

§ 405.1871 [Amended]

■ 20. Section 405.1871 is amended in paragraph (a)(5) by removing the phrase ''must be mailed'' and adding in its place is the phrase ''must be sent''.

§ 405.1875 [Amended]

■ 21. Section 405.1875 is amended—

■ a. In paragraph (c)(1)(iv) by removing the phrase ''must be mailed'' and adding in its place is the phrase ''must be sent''; and

■ b. In paragraph (e)(2) by removing the phrase ''mail a copy'' and adding in its place is the phrase ''send a copy''.

§ 405.1885 [Amended]

■ 22. Section 405.1885 is amended—

■ a. In paragraph (b)(1) by removing the phrase ''of this subpart'' and removing the term ''mailed'' and adding in its place the term ''sent'' each time it appears; and

■ b. In paragraph (b)(2)(i) by removing the phrase ''request to reopen is conclusively presumed to be the date of delivery by a nationally-recognized next-day courier, or the date stamped ''Received'' by CMS, the contractor or the reviewing entity (where a nationally-recognized next-day courier is not employed),'' and adding in its place the phrase ''request to reopen is determined by applying the date of receipt presumption criteria for reviewing entities defined in § 405.1801(a),''.

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 23. The authority citation for part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 24. Section 412.1 is amended by revising paragraph (a)(1) to read as follows:

§ 412.1 Scope of part.

(a) * * *

(1) This part implements sections 1886(d) and (g) of the Act by establishing a prospective payment system for the operating costs of inpatient hospital services furnished to Medicare beneficiaries in cost reporting periods beginning on or after October 1, 1983 and a prospective payment system for the capital-related costs of inpatient hospital services furnished to Medicare beneficiaries in cost reporting periods beginning on or after October 1, 1991.

(i) Under these prospective payment systems, payment for the operating and capital-related costs of inpatient hospital services furnished by hospitals subject to the systems (generally, short-term, acute-care hospitals) is made on the basis of prospectively determined rates and applied on a per discharge basis.

(ii) Payment for other costs related to inpatient hospital services (organ acquisition costs incurred by hospitals with approved organ transplantation centers, the costs of qualified nonphysician anesthetist's services, as described in § 412.113(c), direct costs of approved nursing and allied health educational programs, costs related to

hematopoietic stem cell acquisition for the purpose of an allogeneic hematopoietic stem cell transplant as described in § 412.113(e)) is made on a reasonable cost basis.

(iii) Payment for the direct costs of graduate medical education is made on a per resident amount basis in accordance with §§ 413.75 through 413.83 of this chapter.

(iv) Additional payments are made for outlier cases, bad debts, indirect medical education costs, and for serving a disproportionate share of low-income patients.

(v) Under either prospective payment system, a hospital may keep the difference between its prospective payment rate and its operating or capital-related costs incurred in furnishing inpatient services, and the hospital is at risk for inpatient operating or inpatient capital-related costs that exceed its payment rate.

* * * * *

■ 25. Section 412.2 is amended by adding paragraph (e)(6) to read as follows:

§ 412.2 Basis of payment.

* * * * *

(e) * * *

(6) For cost reporting periods beginning on or after October 1, 2020, the costs of allogenic hematopoietic stem cell acquisition, as described in § 412.113(e), for the purpose of an allogeneic hematopoietic stem cell transplant.

* * * * *

■ 26. Section 412.64 is amended by adding paragraph (e)(5) to read as follows:

§ 412.64 Federal rates for inpatient operating costs for Federal fiscal year 2005 and subsequent fiscal years.

* * * * *

(e) * * *

(5) CMS makes an adjustment to the standardized amount to ensure that the reasonable cost based payments for allogeneic hematopoietic stem cell acquisition costs are made in a manner so that aggregate payments to hospitals are not affected.

* * * * *

§ 412.82 [Amended]

■ 27. Section 412.82 is amended in paragraph (c) by removing the reference ''§ 412.86'' and adding in its place ''§ 412.83''.

■ 28. Section 412.85 and an undesignated center heading preceeding the section are added to read as follows:

Payment Adjustment for Certain Clinical Trials Cases

§ 412.85 Payment adjustment for certain clinical trial cases.

(a) *General rule.* For discharges occurring on or after October 1, 2020, the amount of payment for a discharge described in paragraph (b) of this section is adjusted as described in paragraph (c) of this section.

(b) *Discharges subject to payment adjustment.* Payment is adjusted in accordance with paragraph (c) of this section for discharges assigned to MS–DRG 018 that are part of a clinical trial as determined by CMS based on the reporting of a diagnosis code indicating the encounter is part of a clinical research program on the claim for the discharge.

(c) *Adjustment.* The DRG weighting factor determined under § 412.60(b) is adjusted by a factor that reflects the average cost for cases to be assigned to MS–DRG 018 that are part of a clinical trial to the average cost for cases to be assigned to MS–DRG 018 that are not part of a clinical trial.

§ 412.86 [Redesignated as § 412.83]

■ 29. Section 412.86 is redesignated as § 412.83.

§ 412.86 [Added and Reserved]

■ 29a. New reserved § 412.86 is added.

■ 30. Section 412.87 is amended—

■ a. By revising paragraphs (c)(1), (d) introductory text, (d)(1), (e) introductory text, and (e)(2); and

■ b. By adding paragraph (e)(3).

The revisions and addition read as follows:

§ 412.87 Additional payment for new medical services and technologies: General provisions.

* * * * *

(c) * * *

(1) A new medical device is part of the Food and Drug Administration's (FDA) Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.

* * * * *

(d) *Eligibility criteria for alternative pathway for certain antimicrobial products.* (1)(i) A new medical product is designated by the FDA as a Qualified Infectious Disease Product and has received marketing authorization for the indication covered by the Qualified Infectious Disease Product designation; or

(ii) For discharges occurring on or after October 1, 2021, a new medical product is approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) and used for the indication approved under the LPAD pathway.

* * * * *

(e) *Announcement of determinations and deadline for consideration of new medical service or technology applications, and conditional approval for certain antimicrobial products.*

* * *

(2) Except as provided for in paragraph (e)(3) of this section, CMS only considers, for add-on payments for a particular fiscal year, an application for which the new medical service or technology has received FDA marketing authorization by July 1 prior to the particular fiscal year.

(3) A technology for which an application is submitted under an alternative pathway for certain antimicrobial products under paragraph (d) of this section that does not receive FDA marketing authorization by the July 1 deadline specified in paragraph (e)(2) of this section may be conditionally approved for the new technology add-on payment for a particular fiscal year, effective for discharges beginning in the first quarter after FDA marketing authorization is granted, provided that FDA marketing authorization is granted before July 1 of the fiscal year for which the applicant applied for new technology add-on payments.

■ 31. Section 412.88 is amended—

■ a. In paragraph (a)(2)(ii)(A) introductory text by removing the reference ''paragraph (a)(2)(ii)(*2*) of this section'' and adding in its place ''paragraph (a)(2)(ii)(B) of this section'';

■ b. By revising paragraphs (a)(2)(ii)(B) introductory text and (b)(2).

The revisions read as follows:

§ 412.88 Additional payment for new medical service or technology.

(a) * * *

(2) * * *

(ii) * * *

(B) For a medical product designated by FDA as a Qualified Infectious Disease Product or, for discharges occurring on or after October 1, 2020, for a product approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs, if the costs of the discharge (determined by applying the operating cost-to-charge ratios as described in § 412.84(h)) exceed the full DRG payment, an additional amount equal to the lesser of—

* * * * *

(b) * * *

(2) *For discharges occurring on or after October 1, 2019.* Unless a discharge case qualifies for outlier payment under § 412.84, Medicare will not pay any additional amount beyond the DRG payment plus—

(i) 65 percent of the estimated costs of the new medical service or technology;

(ii) For a medical product designated by FDA as a Qualified Infectious Disease Product, 75 percent of the estimated costs of the new medical service or technology; or

(iii) For discharges occurring on or after October 1, 2020, for a product approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs, 75 percent of the estimated costs of the new medical service or technology.

■ 32. Section 412.92 is amended by revising paragraph (c)(3) to read as follows:

§ 412.92 Special treatment: Sole community hospitals.

* * * * *

(c) * * *

(3) The term *service area* means the area from which a hospital draws at least 75 percent of its inpatients during the most recent 12-month cost reporting period ending before it applies for classification as a sole community hospital. If the most recent cost reporting period ending before the hospital applies for classification as a sole community hospital is for less than 12 months, the hospital's most recent 12-month or longer cost reporting period before the short period is used.

* * * * *

■ 33. Section 412.96 is amended by adding paragraph (c)(2)(iii) to read as follows:

§ 412.96 Special treatment: Referral centers.

* * * * *

(c) * * *

(2) * * *

(iii) If the hospital's cost reporting period that began during the same fiscal year as the cost reporting periods used to compute the regional median discharges under paragraph (i) of this section is for less than 12 months or longer than 12 months, the hospital's number of discharges for that cost reporting period will be annualized to estimate the total number of discharges for a 12-month cost reporting period.

* * * * *

■ 34. Section 412.104 is amended by revising paragraph (a) to read as follows:

§ 412.104 Special treatment: Hospitals with high percentage of ESRD discharges.

(a) *Criteria for classification.* CMS provides an additional payment to a hospital for inpatient services provided to ESRD beneficiaries who receive a dialysis treatment during a hospital stay, if the hospital has established that ESRD beneficiary discharges, excluding discharges classified into any of the following MS–DRGs, where the beneficiary received dialysis services during the inpatient stay, constitute 10 percent or more of its total Medicare discharges:

(1) MS–DRG 019 (Simultaneous Pancreas/Kidney Transplant with Hemodialysis).

(2) MS–DRGs 650 and 651 (Kidney Transplant with Hemodialysis with MCC, without MCC, respectively).

(3) MS–DRGs 682, 683, and 684 (Renal Failure with MCC, with CC, without CC/MCC, respectively).

* * * * *

§ 412.105 [Amended]

■ 35. Section 412.105(f)(1)(ix)(A) is amended—

■ a. By removing the phrase ''to reflect residents added because'' and added in its place the phrase ''to reflect displaced residents added because'' each time it appears.

■ b. By removing the citations ''§§ 413.79(h)(1) and (h)(2)'', ''§§ 413.79(h)(1) and (h)(3)(ii)'', and ''§§ 413.79(h)(1) and (h)(3)(i)'' and adding in their places the citations ''§ 413.79(h)(1) and (2)'', ''§ 413.79(h)(1) and (h)(3)(ii)'', and ''§ 413.79(h)(1) and (h)(3)(i)'', respectively.

■ 36. Section 412.106 is amended by removing the semicolon at the end of paragraph (g)(1)(iii)(C)(*6*) and adding a period in its place and adding paragraphs (g)(1)(iii)(C)(*7*) and (*8*) to read as follows:

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(g) * * *

(1) * * *

(iii) * * *

(C) * * *

(*7*) For fiscal year 2021, CMS will base its estimates of the amount of hospital uncompensated care on data on uncompensated care costs, defined as charity care costs plus non-Medicare and non-reimbursable Medicare bad debt costs from 2017 cost reports from the most recent Hospital Cost Report Information System (HCRIS) database extract, except that, for Puerto Rico hospitals and Indian Health Service or Tribal hospitals, CMS will base its estimates on utilization data for Medicaid and Medicare Supplemental Security Income (SSI) patients, as determined by CMS in accordance with paragraphs (b)(2)(i) and (b)(4) of this section, using data on Medicaid utilization from 2013 cost reports from the most recent HCRIS database extract and the most recent available year of data on Medicare SSI utilization (or, for Puerto Rico hospitals, a proxy for Medicare SSI utilization data).

(*8*) For each subsequent fiscal year, for all eligible hospitals, except Indian Health Service and Tribal hospitals, CMS will base its estimates of the amount of hospital uncompensated care on data on uncompensated care costs, defined as charity care costs plus non-Medicare and non-reimbursable Medicare bad debt costs from cost reports from the most recent cost reporting year for which audits have been conducted.

* * * * *

■ 37. Section 412.113 is amended by adding paragraph (e) to read as follows:

§ 412.113 Other payments.

* * * * *

(e) *Allogeneic hematopoietic stem cell acquisition.* For cost reporting periods beginning on or after October 1, 2020, in the case of a subsection (d) hospital that furnishes an allogeneic hematopoietic stem cell transplant to an individual, payment to such hospital for hematopoietic stem cell acquisition costs is made on a reasonable cost basis.

(1) An allogeneic hematopoietic stem cell transplant is the intravenous infusion of hematopoietic cells derived from bone marrow, peripheral blood stem cells, or cord blood, but not including embryonic stem cells, of a donor to an individual that are or may be used to restore hematopoietic function in such individual having an inherited or acquired deficiency or defect.

(2) Allogeneic hematopoietic stem cell acquisition costs recognized under this paragraph (e) are costs of acquiring hematopoietic stem cells from a donor. These costs are as follows:

(i) Registry fees from a national donor registry described in 42 U.S.C. 274k, if applicable, for stem cells from an unrelated donor.

(ii) Tissue typing of donor and recipient.

(iii) Donor evaluation.

(iv) Physician pre-admission/pre-procedure donor evaluation services.

(v) Costs associated with the collection procedure (for example, general routine and special care services, procedure/operating room and other ancillary services, apheresis services).

(vi) Post-operative/post-procedure evaluation of donor.

(vii) Preparation and processing of stem cells derived from bone marrow, peripheral blood stem cells, or cord blood (but not including embryonic stem cells).

(3) A subsection (d) hospital that furnishes allogeneic hematopoietic stem cell transplants is required to formulate a standard acquisition charge that approximates the hospital's average cost of acquiring hematopoietic stem cells for all of its allogeneic hematopoietic stem cell transplants. Actual charges are converted to reasonable cost using the corresponding ancillary cost-to-charge ratios.

(4) The hospital's Medicare share of the allogeneic hematopoietic stem cell acquisition costs is based on the ratio of the number of its allogeneic hematopoietic stem cell transplants furnished to Medicare beneficiaries to the total number of its allogeneic hematopoietic stem cell transplants furnished to all patients, regardless of payer, which is applied to reasonable cost.

(5) A subsection (d) hospital must maintain an itemized statement that identifies the services furnished in collecting hematopoietic stem cells, the charges, the person receiving the service (donor/recipient; if donor the provider must identify the prospective recipient), and the prospective recipient's health care insurance number.

■ 38. Section 412.115 is amended by revising paragraph (c) to read as follows:

§ 412.115 Additional payments.

* * * * *

(c) *QIO reimbursement for cost of sending requested patient records to the QIO.* An additional payment is made to a hospital in accordance with § 476.78 of this chapter for the costs of sending requested patient records to the QIO in electronic format, by facsimile, or by photocopying and mailing.

■ 39. Section 412.152 is amended by revising the definitions of ''Applicable period'' and ''Applicable period for dual eligibility'' to read as follows:

§ 412.152 Definitions for the Hospital Readmissions Reduction Program.

* * * * *

Applicable period is, with respect to a fiscal year, the 3-year period (specified by the Secretary) from which data are collected in order to calculate excess readmission ratios and adjustments under the Hospital Readmissions Reduction Program.

(1) The applicable period for FY 2022 is the 3-year period from July 1, 2017 through June 30, 2020; and

(2) Beginning with the FY 2023 program year, the applicable period is the 3-year period advanced by 1-year from the prior year's period from which data are collected in order to calculate excess readmission ratios and adjustments under the Hospital Readmissions Reduction Program, unless otherwise specified by the Secretary. That is, for FY 2023, the applicable period is the 3-year period from July 1, 2018 through June 30, 2021.

Applicable period for dual eligibility is the 3-year data period corresponding to the applicable period for the Hospital Readmissions Reduction Program, unless otherwise established by the Secretary.

* * * * *

■ 40. Section 412.170 is amended by revising the definition of ''Applicable period'' and adding the definitions of ''CDC NHSN HAI'' and ''CMS PSI 90'' in alphabetical order to read as follows:

§ 412.170 Definitions for the Hospital-Acquired Condition Reduction Program.

* * * * *

Applicable period is, unless otherwise specified by the Secretary, with respect to a fiscal year, the 2-year period (specified by the Secretary) from which data are collected in order to calculate the total hospital-acquired condition score under the Hospital-Acquired Condition Reduction Program.

(1) The applicable period for FY 2023—

(i) For the CMS PSI 90 measure is the 24-month period from July 1, 2019 through June 30, 2021; and

(ii) For the CDC NHSN HAI measures is the 24-month period from January 1, 2020 through December 31, 2021.

(2) Beginning with the FY 2023 program year, the applicable period is the 24-month period advanced by 1-year from the prior fiscal year's period from which data are collected in order to calculate the total hospital-acquired condition score under the Hospital-Acquired Condition Reduction Program, unless otherwise specified by the Secretary.

CDC NHSN HAI stands for Centers for Disease Control and Prevention National Healthcare Safety Network healthcare-associated infection measures.

CMS PSI 90 stands for Patient Safety and Adverse Events Composite for Selected Indicators (modified version of PSI 90).

* * * * *

■ 41. Section 412.230 is amended by revising paragraph (d)(2)(ii)(A) to read as follows:

§ 412.230 Criteria for an individual hospital seeking redesignation to another rural area or an urban area.

* * * * *

(d) * * *

(2) * * *

(ii) * * *

(A) For hospital-specific data, the hospital must provide a weighted 3-year average of its average hourly wages using data from the CMS hospital wage survey used to construct the wage index in effect for prospective payment purposes.

(*1*) For the limited purpose of qualifying for geographic reclassification based on wage data from cost reporting periods beginning prior to FY 2000, a hospital may request that its wage data be revised if the hospital is in an urban area that was subject to the rural floor for the period during which the wage data the hospital wishes to revise were used to calculate its wage index.

(*2*) Once a hospital has accumulated at least 1 year of wage data in the applicable 3-year average hourly wage period used by the MGCRB, the hospital is eligible to apply for reclassification based on those data.

* * * * *

■ 42. Section 412.278 is amended by revising paragraph (b)(1) to read as follows:

§ 412.278 Administrator's review.

* * * * *

(b) * * *

(1) The hospital's request for review must be in writing and sent to the Administrator, in care of the Office of the Attorney Advisor. The request must be received by the Administrator within 15 days after the date the MGCRB issues its decision. The hospital must also submit an electronic copy of its request for review to to CMS's Hospital and Ambulatory Policy Group.

* * * * *

■ 43. Section 412.312 is amended by adding paragraph (f) to read as follows:

§ 412.312 Payment based on the Federal rate.

* * * * *

(f) *Payment adjustment for certain clinical trial cases.* For discharges occurring on or after October 1, 2020, in determining the payment amount under this section for certain clinical trial cases as described in § 412.85(b), the DRG weighting factor described in paragraph (b)(1) of this section is adjusted as described in § 412.85(c).

■ 44. Section 412.523 is amended by adding paragraph (c)(3)(xvii) to read as follows:

§ 412.523 Methodology for calculating the Federal prospective payment rates.

* * * * *

(c) * * *

(3) * * *

(xvii) *For long-term care prospective payment system fiscal year 2021 and subsequent fiscal years.* The long-term care hospital prospective payment

system standard Federal payment rate for a long-term care hospital prospective payment system fiscal year is the standard Federal payment rate for the previous long-term care prospective payment system fiscal year updated by the percentage increase in the market basket index (as determined by CMS) less a multifactor productivity adjustment (as determined by CMS), and further adjusted, as appropriate, as described in paragraph (d) of this section.

* * * * *

■ 45. Section 412.622 is amended by revising paragraph (b)(2)(i) to read as follows:

§ 412.622 Basis of payment.

* * * * *

(b) * * *

(2) * * *

(i) Bad debts of Medicare beneficiaries, as provided in § 413.89 of this chapter; and

* * * * *

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

■ 46. 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.

■ 47. Section 413.20 is amended by revising paragraph (d)(3) to read as follows:

§ 413.20 Financial data and reports.

* * * * *

(d) * * *

(3)(i) The provider must furnish the contractor—

(A) Upon request, copies of patient service charge schedules and changes thereto as they are put into effect; and

(B) Its median payer-specific negotiated charge by MS–DRG for payers that are Medicare Advantage (MA) organizations, and its median payer-specific negotiated charge by MS–DRG for all third party payers, as applicable, and changes thereto as they are put into effect.

(ii) The contractor evaluates the charge schedules as specified in paragraph (d)(3)(i) of this section to determine the extent to which they may be used for determining program payment.

* * * * *

■ 48. Section 413.79 is amended by adding paragraph (h)(1)(iii) to read as follows:

§ 413.79 Direct GME payments: Determination of the weighted number of FTE residents.

* * * * *

(h) * * *

(1) * * *

(iii) *Displaced resident* means a resident who—

(A) Leaves a program after the hospital or program closure is publicly announced, but before the actual hospital or program closure;

(B) Is assigned to and training at planned rotations at another hospital who will be unable to return to his/her rotation at the closing hospital or program;

(C) Is matched into a GME program at the closing hospital or program but has not yet started training at the closing hospital or program;

(D) Is physically training in the hospital on the day prior to or day of program or hospital closure; or

(E) Is on approved leave at the time of the announcement of closure or actual closure, and therefore, cannot return to his/her rotation at the closing hospital or program.

* * * * *

■ 49. Section 413.89 is amended by revising paragraphs (b), (c), (e)(2), and (f) to read as follows:

§ 413.89 Bad debts, charity, and courtesy allowances.

* * * * *

(b) *Definitions*—(1) *Bad debts.* (i) For cost reporting periods beginning before October 1, 2020:

(A) Bad debts are amounts considered to be uncollectible from accounts and notes receivable that were created or acquired in providing services.

(B) ''Accounts receivable'' and ''notes receivable'' are designations for claims arising from the furnishing of services, and are collectible in money in the relatively near future.

(ii) For cost reporting periods beginning on or after October 1, 2020, bad debts are amounts considered to be uncollectible from patient accounts that were created or acquired in providing services and are categorized as implicit price concessions for cost reporting purposes and are recorded in the provider's accounting records as a component of net patient revenue.

(2) *Charity allowances.* Charity allowances are reductions in charges made by the provider of services because of the indigence or medical indigence of the patient. Cost of free care (uncompensated services) furnished under a Hill–Burton obligation are considered as charity allowances.

(3) *Courtesy allowances.* Courtesy allowances indicate a reduction in charges in the form of an allowance to physicians, clergy, members of religious orders, and others as approved by the governing body of the provider, for services received from the provider. Employee fringe benefits, such as hospitalization and personnel health programs, are not considered to be courtesy allowances.

(c) *Normal accounting treatment: Reduction in revenue.* (1) Effective for cost reporting periods beginning before October 1, 2020, bad debts, charity, and courtesy allowances represent reductions in revenue. The failure to collect charges for services furnished does not add to the cost of providing the services. Such costs have already been incurred in the production of the services.

(2) Effective for cost reporting periods beginning on or after October 1, 2020, bad debts, also known as ''implicit price concessions,'' charity, and courtesy allowances represent reductions in revenue. The failure to collect charges for services furnished does not add to the cost of providing the services. Such costs have already been incurred in the production of the services.

(3) Effective for cost reporting periods beginning on or after October 1, 2020, Medicare bad debts must not be written off to a contractual allowance account but must be charged to an expense account for uncollectible accounts.

* * * * *

(e) * * *

(2) The provider must be able to establish that reasonable collection efforts were made.

(i) *Non-indigent beneficiary.* A non-indigent beneficiary is a beneficiary who has not been determined to be categorically or medically needy by a State Medicaid Agency to receive medical assistance from Medicaid, nor have they been determined to be indigent by the provider for Medicare bad debt purposes. To be considered a reasonable collection effort for non-indigent beneficiaries all of the following are applicable:

(A) A provider's collection effort or the effort of a collection agency acting on the provider's behalf, or both, to collect Medicare deductible or coinsurance amounts must consist of all of the following:

(*1*) Be similar to the collection effort put forth to collect comparable amounts from non-Medicare patients.

(*2*) For cost reporting periods beginning before October 1, 2020, involve the issuance of a bill to the beneficiary or the party responsible for the beneficiary's personal financial obligations on or shortly after discharge or death of the beneficiary.

(*3*) For cost reporting periods beginning on or after October 1, 2020, involve the issuance of a bill to the beneficiary or the party responsible for the beneficiary's personal financial obligations on or before 120 days after the latter of one of the following:

(*i*) The date of the Medicare remittance advice.

(*ii*) The date of the remittance advice from the beneficiary's secondary payer, if any.

(*4*) Include other actions such as subsequent billings, collection letters and telephone calls or personal contacts with this party which constitute a genuine, rather than token, collection effort.

(*5*)(*i*) Last at least 120 days after paragraph (e)(2)(i)(A)(*2*) or (*3*) of this section is met before being written off as uncollectible under paragraph (e)(3) of this section.

(*ii*) Start a new 120-day collection period each time a partial payment is received within a 120-day collection period until the remaining unpaid amount is paid in full or remains unpaid after 120 days.

(*6*) Maintaining and, upon request, furnishing documentation to its contractor that includes all of the following:

(*i*) The provider's bad debt collection policy which describes the collection process for Medicare and non-Medicare patients.

(*ii*) The patient account history documents which show the dates of various collection actions such as the issuance of bills to the beneficiary, follow-up collection letters, reports of telephone calls and personal contact, etc.

(*iii*) The beneficiary's file with copies of the bill(s) and follow-up notices.

(B) A provider that uses a collection agency to perform its collection effort must do all of the following:

(*1*) Reduce the beneficiary's account receivable by the gross amount collected.

(*2*) Include any fee charged by the collection agency as an administrative cost.

(*3*) Before claiming the unpaid amounts as a Medicare bad debt, cease all collection efforts, including the collection agency efforts, and ensure that the collection accounts have been returned to the provider from the agency.

(ii) *Indigent non-dual eligible beneficiary.* An indigent non-dual eligible beneficiary is a beneficiary who is determined to be indigent or medically indigent by the provider and is not eligible for Medicaid as categorically or medically needy.

(A) To determine a beneficiary to be an indigent non-dual eligible beneficiary, the provider must do all of the following:

(*1*) Not use a beneficiary's declaration of their inability to pay their medical bills or deductibles and coinsurance amounts as sole proof of indigence or medical indigence.

(*2*) Take into account a beneficiary's total resources which include, but are not limited to, an analysis of all of the following:

(*i*) Assets (only those convertible to cash and unnecessary for the beneficiary's daily living).

(*ii*) Liabilities.

(*iii*) Income.

(*iv*) Expenses.

(*3*) Consider any extenuating circumstances that would affect the determination of the beneficiary's indigence or medical indigence.

(*4*) Determine that no source other than the beneficiary would be legally responsible for the beneficiary's medical bill, such as a legal guardian or State Medicaid program.

(*5*) Maintain and, upon request, furnish its contractor its indigence policy describing the method by which indigence or medical indigence is determined and all the beneficiary specific documentation which supports the provider's determination of each beneficiary's indigence or medical indigence.

(B) Once indigence is determined and the provider concludes that there has been no improvement in the beneficiary's financial status, the bad debt may be deemed uncollectible without applying a collection effort.

(iii) *Indigent dual-eligible beneficiaries (including qualified Medicare beneficiaries).* Providers may deem Medicare beneficiaries indigent or medically indigent when such individuals have also been determined eligible for Medicaid under a State's Title XIX Medicaid program as either categorically needy individuals or medically needy individuals. To be considered a reasonable collection effort for dual-eligible beneficiaries, a provider—

(A) Must determine whether the State's Title XIX Medicaid Program (or a local welfare agency, if applicable) is responsible to pay all or a portion of the beneficiary's Medicare deductible or coinsurance amounts;

(B) Must submit a bill to its Medicaid/Title XIX agency (or to its local welfare agency) to determine the State's cost sharing obligation to pay all or a portion of the applicable Medicare deductible and coinsurance;

(C) Must submit the Medicaid remittance advice received from the State to its Medicare contractor;

(D) Must reduce allowable Medicare bad debt by any amount that the State is obligated to pay, either by statute or under the terms of its approved Medicaid State plan, regardless of whether the State actually pays its obligated amount to the provider; and

(E) May include the Medicare deductible or coinsurance amount, or any portion thereof that the State is not obligated to pay, and which remains unpaid by the beneficiary, as an allowable Medicare bad debt.

(f) *Reporting period for writing off bad debts and reporting of recoveries of bad debts reimbursed in prior periods.* For cost reporting periods beginning before, on, or after October 1, 2020, the deductible and coinsurance amounts uncollected from beneficiaries are to be written off and recognized as allowable bad debts in the cost reporting period in which the accounts are deemed to be worthless.

(1) Any payment on the account made by the beneficiary or a responsible party, after the write-off date but before the end of the cost reporting period, must be used to reduce the final bad debt for the account claimed in that cost report.

(2) In some cases an amount written off as a bad debt and reimbursed by the program in a prior cost reporting period may be recovered in a subsequent period.

(i) In situations described in this paragraph (f)(2), the recovered amount must be used to reduce the provider's reimbursable costs in the period in which the amount is recovered.

(ii) The amount of reduction in the period of recovery (as specified in paragraph (f)(2)(i) of this section) must not exceed the actual amount reimbursed by the program for the related bad debt in the applicable prior cost reporting period.

* * * * *

■ 50. Section 413.355 is revised to read as follows:

§ 413.355 Additional payment: QIO reimbursement for cost of sending records electronically or by photocopy and mailing.

An additional payment is made to a skilled nursing facility in accordance

with § 476.78 of this chapter for the costs of sending requested patient records to the QIO in electronic format, by facsimile, or by photocopying and mailing.

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 51. The authority citation for part 417 is revised to read as follows:

Authority: 42 U.S.C. 300e, 300e–5, 300e–91302 and 1395hh), and 31 U.S.C. 9701.

■ 52. Section 417.536 is amended by revising paragraph (g) to read as follows:

§ 417.536 Cost payment principles.

* * * * *

(g) *Charity and courtesy allowances.* As specified in § 413.89 of this chapter, charity and courtesy allowances are deductions from revenue and may not be included as allowable costs.

* * * * *

PART 476—QUALITY IMPROVEMENT ORGANIZATION REVIEW

■ 53. The authority citation for part 476 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 54. Section 476.78 is amended—

■ a. In paragraph (b)(2)(i) by removing the phrase ''photocopy and deliver to the QIO'' and adding in its place ''deliver to the QIO'';

■ b. By revising paragraphs (b)(2)(ii) and (c);

■ c. By redesignating paragraph (d) as paragraph (f);

■ d. By adding new paragraph (d) and paragraph (e); and

■ e. By revising newly redesignated paragraph (f).

The revisions and additions read as follows:

§ 476.78 Responsibilities of providers and practitioners.

* * * * *

(b) * * *

(2) * * *

(ii) Except if granted a waiver as described in paragraph (d) of this section, send secure transmission of an electronic version of each requested patient record to the QIO.

(A) Providers and practitioners must deliver electronic versions of patient records within 14 calendar days of the request.

(B) A QIO is authorized to require the receipt of the patient records earlier than the 14-day timeframe if the QIO makes a preliminary determination that the review involves a potential gross and flagrant or substantial violation as specified in part 1004 of this title and circumstances warrant earlier receipt of the patient records.

(C) A practitioner's or provider's failure to comply with the request for patient records within the established timeframe may result in the QIO taking action in accordance with § 476.90.

* * * * *

(c) *Submission of patient records in electronic format.* Except as specified in paragraph (d) of this section, a provider or practitioner must deliver patient records requested by a QIO for the purpose of fulfilling one or more QIO functions, in an electronic format, using the mechanism specified by the QIO. In the absence of any mechanism specified by the requesting QIO, the requested patient records must be submitted using any CMS-approved mechanism.

(d) *Waiver from the requirement to submit patient records in an electronic format.* (1) A provider or practitioner that lacks the capability to submit requested patient records to the requesting QIO in an electronic format may request a waiver from the requirements in paragraph (c) of this section.

(i) For providers that are required to execute a written agreement with the QIO, a request for a waiver must be made during execution of the written agreement with the QIO.

(ii) Providers that are required to execute a written agreement with the QIO must request a waiver by notifying the QIO that they lack the capability to submit patient records in electronic format, if their lack of capability arises after the written agreement is executed.

(iii) Upon approval of the waiver, the waiver becomes part of the written agreement with the QIO.

(iv) A provider with an approved waiver may submit patient records by facsimile or by photocopying and mailing to the QIO.

(v) A provider with an approved waiver may be reimbursed by the QIO for patient records submitted by facsimile or by photocopying and mailing in accordance with paragraph (e)(2) of this section.

(vi) A QIO may not reimburse for any patient record submitted to the QIO by facsimile or by photocopying and mailing if the provider does not have an approved waiver.

(2) Providers and practitioners that are not required to execute a written agreement with the QIO may request a waiver to be exempted from submitting patient records in an electronic format.

(i) Such providers and practitioners may request a waiver by notifying the QIO that they lack the capability to submit patient records in electronic format.

(ii) Upon approval of the waiver, a provider or practitioner may submit patient records by facsimile or by photocopying and mailing to the QIO.

(iii) Providers and practitioners with approved waivers may be reimbursed by the QIO for patient records submitted by facsimile or by photocopying and mailing in accordance with paragraph (e)(2) of this section.

(iv) A QIO may not reimburse for any patient records submitted to the QIO by facsimile or by photocopying and mailing, if the provider or practitioner does not have an approved waiver.

(e) *Reimbursement for submitting patient records to the QIO.* (1) For purposes of this paragraph (e), a *patient record* means all patient care data and other pertinent data or information relating to care or services provided to an individual patient in the possession of the provider or practitioner, as requested by a QIO for the purpose of performing one or more QIO functions.

(2) A QIO may reimburse a provider or practitioner for requested patient records submitted in an electronic format, at the rate of $3.00 per patient record.

(3) For a provider or practitioner that has an approved waiver under paragraph (d) of this section, a QIO may reimburse the provider or practitioner for requested records submitted by—

(i) Facsimile at the rate of $0.15 per page; or

(ii) Photocopying and mailing at the rate of $0.15 per page, plus the cost of first class postage.

(4) A QIO may only reimburse a provider or practitioner once for each patient record submitted, per request, even if a patient record is submitted using multiple formats, in fragments, or more than once in response to a single request by the QIO.

(f) *Appeals.* Reimbursement for the costs of submitting requested patient records to the QIO in electronic format, by facsimile or by photocopying and mailing is an additional payment to providers under the prospective payment system, as specified in §§ 412.115, 413.355, and 484.265 of this chapter. Appeals concerning these costs are subject to the review process specified in part 405, subpart R, of this chapter.

PART 480—ACQUISITION, PROTECTION, AND DISCLOSURE OF QUALITY IMPROVEMENT ORGANIZATION INFORMATION

■ 55. The authority citation for part 480 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 56. Section 480.111 is amended by revising paragraph (d) to read as follows:

§ 480.111 QIO access to records and information of institutions and practitioners.

* * * * *

(d)(1) When submitting patient records to the QIO under this section, the institution or practitioner must do so consistent with the requirements in § 476.78(c) and (d) of this chapter.

(2) Reimbursement to an institution or practitioner for the cost of providing patient records is paid in accordance with § 476.78(e) of this chapter.

PART 484—HOME HEALTH SERVICES

■ 57. The authority citation for part 484 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh unless otherwise noted.

■ 58. Section 484.265 is revised to read as follows:

§ 484.265 Additional payment.

An additional payment is made to a home health agency in accordance with § 476.78 of this chapter for the costs of sending requested patient records to the QIO in electronic format, by facsimile, or by photocopying and mailing.

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 59. The authority citation for part 495 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 60. Section 495.4 is amended in the definition of ''EHR reporting period for a payment adjustment year'' by adding paragraphs (2)(vi) and (3)(vi) to read as follows:

§ 495.4 Definitions.

* * * * *

EHR reporting period for a payment adjustment year. * * *

(2) * * *

(vi) The following are applicable for 2022:

(A) If an eligible hospital has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2022 and applies for the FY 2023 and 2024 payment adjustment years. For the FY 2023 payment adjustment year, the EHR reporting period must end before and the eligible hospital must successfully register for and attest to meaningful use no later than October 1, 2022.

(B) If in a prior year an eligible hospital has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within CY 2022 and applies for the FY 2024 payment adjustment year.

(3) * * *

(vi) The following are applicable for 2022:

(A) If a CAH has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2022 and applies for the FY 2022 payment adjustment year.

(B) If in a prior year a CAH has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within CY 2022 and applies for the FY 2022 payment adjustment year.

* * * * *

§ 495.20 [Amended]

■ 61. Section 495.20 is amended—

■ a. In paragraph (e)(5)(iii) by removing the reference ''45 CFR 170.304(g)'' and adding in its place the reference ''45 CFR 170.314(g)''; and

■ b. In paragraph (l)(11)(ii)(C)(*1*) by removing the reference ''45 CFR 107.314(b)(2)'' and adding in its place the reference ''45 CFR 170.314(b)(2)''.

■ 62. Section 495.24 to be amended by revising paragraph (e)(5)(iii)(B) and the heading for paragraph (e)(6)(ii)(B) to read as follows:

§ 495.24 Stage 3 meaningful use objectives and measures for EPs, eligible hospitals and CAHs for 2019 and subsequent years.

* * * * *

(e) * * *

(5) * * *

(iii) * * *

(B) *Query of prescription drug monitoring program (PDMP) measure.* Subject to paragraph (e)(3) of this section, for at least one Schedule II opioid electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a Prescription Drug Monitoring Program (PDMP) for prescription drug history, except where prohibited and in accordance with applicable law. This measure is worth 5 bonus points in CYs 2019, 2020, and 2021.

* * * * *

(6) * * *

(ii) * * *

(B) *Support electronic referral loops by receiving and reconciling health information measure.* * * *

* * * * *

■ 63. Section 495.104 is amended by revising paragraphs (c)(5)(viii)(B) through (D) to read as follows:

§ 495.104 Incentive payments to eligible hospitals.

* * * * *

(c) * * *

(5) * * *

(viii) * * *

(B) ¾ for FY 2019;

(C) ½ for FY 2020; and

(D) ¼ for FY 2021.

* * * * *

Dated: March 24, 2020.

Seema Verma,

Administrator, Centers for Medicare and Medicaid Services.

Dated: April 9, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

Note: The following Addendum and Appendixes will not appear in the Code of Federal Regulations.

Addendum—Schedule of Standardized Amounts, Update Factors, Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning On or After October 1, 2020, and Payment Rates for LTCHs Effective for Discharges Occurring On or After October 1, 2020

I. Summary and Background

In this Addendum, we are setting forth a description of the methods and data we used to determine the proposed prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs for FY 2021 for acute care hospitals. We also are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS for FY 2021. We note that, because certain hospitals excluded from the IPPS are paid on a reasonable cost basis subject to a rate-of-increase ceiling (and not by the IPPS), these hospitals are not affected by the proposed figures for the standardized amounts, offsets, and budget neutrality factors. Therefore, in this proposed rule, we are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS that will be effective for cost reporting periods beginning on or after October 1, 2020.

In addition, we are setting forth a description of the methods and data we used to determine the proposed LTCH PPS standard Federal payment rate that would be applicable to Medicare LTCHs for FY 2021.

In general, except for SCHs and MDHs, for FY 2021, each hospital's payment per discharge under the IPPS is based on 100 percent of the Federal national rate, also known as the national adjusted standardized amount. This amount reflects the national average hospital cost per case from a base year, updated for inflation.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal national rate (including, as discussed in section IV.G. of

the preamble of this proposed rule, uncompensated care payments under section 1886(r)(2) of the Act); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge.

Under section 1886(d)(5)(G) of the Act, MDHs historically were paid based on the Federal national rate or, if higher, the Federal national rate plus 50 percent of the difference between the Federal national rate and the updated hospital-specific rate based on FY 1982 or FY 1987 costs per discharge, whichever was higher. However, section 5003(a)(1) of Public Law 109–171 extended and modified the MDH special payment provision that was previously set to expire on October 1, 2006, to include discharges occurring on or after October 1, 2006, but before October 1, 2011. Under section 5003(b) of Public Law 109–171, if the change results in an increase to an MDH's target amount, we must rebase an MDH's hospital specific rates based on its FY 2002 cost report. Section 5003(c) of Public Law 109–171 further required that MDHs be paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the updated hospital specific rate. Further, based on the provisions of section 5003(d) of Public Law 109–171, MDHs are no longer subject to the 12-percent cap on their DSH payment adjustment factor. Section 50205 of the Bipartisan Budget Act of 2018 extended the MDH program for discharges on or after October 1, 2017 through September 30, 2022.

As discussed in section IV.B. of the preamble of this proposed rule, in accordance with section 1886(d)(9)(E) of the Act as amended by section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), for FY 2021, subsection (d) Puerto Rico hospitals will continue to be paid based on 100 percent of the national standardized amount. Because Puerto Rico hospitals are paid 100 percent of the national standardized amount and are subject to the same national standardized amount as subsection (d) hospitals that receive the full update, our discussion later in this section does not include references to the Puerto Rico standardized amount or the Puerto Rico-specific wage index.

As discussed in section II. of this Addendum, we are proposing to make changes in the determination of the prospective payment rates for Medicare inpatient operating costs for acute care hospitals for FY 2021. In section III. of this Addendum, we discuss our proposed policy changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2021. In section IV. of this Addendum, we are setting forth the rate-of-increase percentage for determining the rate-of-increase limits for certain hospitals excluded from the IPPS for FY 2021. In section V. of this Addendum, we discuss proposed policy changes for determining the LTCH PPS standard Federal rate for LTCHs paid under the LTCH PPS for FY 2021. The tables to which we refer in the preamble of this proposed rule are listed in section VI. of this Addendum and are available via the internet on the CMS website.

II. Proposed Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2021

The basic methodology for determining prospective payment rates for hospital inpatient operating costs for acute care hospitals for FY 2005 and subsequent fiscal years is set forth under § 412.64. The basic methodology for determining the prospective payment rates for hospital inpatient operating costs for hospitals located in Puerto Rico for FY 2005 and subsequent fiscal years is set forth under §§ 412.211 and 412.212. Later in this section, we discuss the factors we are proposing to use for determining the proposed prospective payment rates for FY 2021.

In summary, the proposed standardized amounts set forth in Tables 1A, 1B, and 1C that are listed and published in section VI. of this Addendum (and available via the internet on the CMS website) reflect—

- Equalization of the standardized amounts for urban and other areas at the level computed for large urban hospitals during FY 2004 and onward, as provided for under section 1886(d)(3)(A)(iv)(II) of the Act.
- The labor-related share that is applied to the standardized amounts to give the hospital the highest payment, as provided for under sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act. For FY 2021, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the national standardized amount. We refer readers to section IV.B. of the preamble of this proposed rule for a complete discussion on the proposed FY 2021 inpatient hospital update. The table that follows shows these four scenarios:

PROPOSED FY 2021 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS				
FY 2021	**Hospital Submitted Quality Data and is a Meaningful EHR User**	**Hospital Submitted Quality Data and is NOT a Meaningful EHR User**	**Hospital Did NOT Submit Quality Data and is a Meaningful EHR User**	**Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User**
Proposed Market Basket Rate-of-Increase	3.0	3.0	3.0	3.0
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.75	-0.75
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-2.25	0	-2.25
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.4	-0.4	-0.4	-0.4
Proposed Applicable Percentage Increase Applied to Standardized Amount	**2.6**	**0.35**	**1.85**	**-0.4**

We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.

In addition, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also to apply the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act to Puerto Rico hospitals that are not meaningful EHR users, effective FY 2022. Accordingly, because the provisions of section 1886(b)(3)(B)(ix) of the Act are not applicable to hospitals located in Puerto Rico until FY 2022, the adjustments under this provision are not applicable for FY 2021.

• An adjustment to the standardized amount to ensure budget neutrality for DRG recalibration and reclassification, as provided for under section 1886(d)(4)(C)(iii) of the Act.

• An adjustment to ensure the wage index and labor-related share changes (depending on the fiscal year) are budget neutral, as provided for under section 1886(d)(3)(E)(i) of the Act (as discussed in the FY 2006 IPPS final rule (70 FR 47395) and the FY 2010 IPPS final rule (74 FR 44005). We note that section 1886(d)(3)(E)(i) of the Act requires that when we compute such budget neutrality, we assume that the provisions of section 1886(d)(3)(E)(ii) of the Act (requiring a 62-percent labor-related share in certain circumstances) had not been enacted.

• An adjustment to ensure the effects of geographic reclassification are budget neutral, as provided for under section 1886(d)(8)(D) of the Act, by removing the FY 2020 budget neutrality factor and applying a revised factor.

• A positive adjustment of 0.5 percent in FYs 2019 through 2023 as required under section 414 of the MACRA.

• An adjustment to ensure the effects of the Rural Community Hospital Demonstration program required under section 410A of Public Law 108–173, as amended by sections 3123 and 10313 of Public Law 111–148, which extended the demonstration program for an additional 5 years, as amended by section 15003 of Public Law 114–255 which amended section 410A of Public Law 108–173 to provide for a 10-year extension of the demonstration program (in place of the 5-year extension required by the Affordable Care Act) beginning on the date immediately following the last day of the initial 5-year period under section 410A(a)(5) of Public Law 108–173, are budget neutral as required under section 410A(c)(2) of Public Law 108–173.

• Beginning with FY 2021, an adjustment to ensure the effects of the reasonable cost based payment for allogeneic hematopoietic stem cell acquisition costs under section 108 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94), are budget neutral as required under section 108 of Public Law 116–94.

• An adjustment to the standardized amount to implement in a budget neutral manner the increase in the wage index values for hospitals with a wage index value below the 25th percentile wage index value across all hospitals (as described in section III.N. of the preamble of this proposed rule).

• As discussed in this section and in section III.2.d of the preamble of this proposed rule, an adjustment to the standardized amount (using our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act) to implement in a budget neutral manner our proposed transition for hospitals negatively impacted due to proposed changes to the wage index (including the proposed implementation of the revised OMB market labor delineations). We refer the reader to section III.2.d. of the preamble of this proposed rule, for a detailed discussion.

• An adjustment to remove the FY 2020 outlier offset and apply an offset for FY 2021, as provided for in section 1886(d)(3)(B) of the Act.

For FY 2021, consistent with current law, we are proposing to apply the rural floor budget neutrality adjustment to hospital wage indexes. Also, consistent with section 3141 of the Affordable Care Act, instead of applying a State-level rural floor budget neutrality adjustment to the wage index, we are proposing to apply a uniform, national budget neutrality adjustment to the FY 2021 wage index for the rural floor.

A. Calculation of the Proposed Adjusted Standardized Amount

1. Standardization of Base-Year Costs or Target Amounts

In general, the national standardized amount is based on per discharge averages of adjusted hospital costs from a base period (section 1886(d)(2)(A) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. The September 1, 1983 interim final rule (48 FR 39763) contained a detailed explanation of how base-year cost data (from cost reporting periods ending during FY 1981) were established for urban and rural hospitals in the initial development of standardized amounts for the IPPS.

Sections 1886(d)(2)(B) and 1886(d)(2)(C) of the Act require us to update base-year per discharge costs for FY 1984 and then standardize the cost data in order to remove the effects of certain sources of cost variations among hospitals. These effects include case-mix, differences in area wage levels, cost-of-living adjustments for Alaska and Hawaii, IME costs, and costs to hospitals serving a disproportionate share of low-income patients.

For FY 2021, we are proposing to continue to use the national labor-related and nonlabor-related shares (which are based on the 2014-based hospital market basket) that were used in FY 2020. Specifically, under section 1886(d)(3)(E) of the Act, the Secretary estimates, from time to time, the proportion of payments that are labor-related and adjusts the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the proportion of hospitals' costs that are attributable to wages and wage-related costs as the ''labor-related share.'' For FY 2021, as discussed in section III. of the preamble of this proposed rule, we are proposing to continue to use a labor-related share of 68.3 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000.

The proposed standardized amounts for operating costs appear in Tables 1A, 1B, and 1C that are listed and published in section VI. of the Addendum to this proposed rule and are available via the internet on the CMS website.

2. Computing the National Average Standardized Amount

Section 1886(d)(3)(A)(iv)(II) of the Act requires that, beginning with FY 2004 and thereafter, an equal standardized amount be computed for all hospitals at the level computed for large urban hospitals during FY 2003, updated by the applicable percentage update. Accordingly, we are proposing to calculate the FY 2021 national average standardized amount irrespective of whether a hospital is located in an urban or rural location.

3. Updating the National Average Standardized Amount

Section 1886(b)(3)(B) of the Act specifies the applicable percentage increase used to update the standardized amount for payment for inpatient hospital operating costs. We note that, in compliance with section 404 of the MMA, in this proposed rule, we are proposing to use the 2014-based IPPS operating and capital market baskets for FY 2021. As discussed in section IV.B. of the preamble of this proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are proposing to reduce the FY 2021 applicable percentage increase (which for this proposed rule is based on IGI's fourth quarter 2019 forecast of the 2014-based IPPS market basket) by the MFP adjustment (the 10-year moving average of MFP for the period ending FY 2021) of 0.4 percentage point, which for this proposed rule is also calculated based on IGI's fourth quarter 2019 forecast.

Based on IGI's fourth quarter 2019 forecast of the hospital market basket increase (as discussed in Appendix B of this proposed rule), the forecast of the hospital market basket increase for FY 2021 for this proposed rule is 3.0 percent. As discussed earlier, for FY 2021, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act, there are four possible applicable percentage increases that can be applied to the standardized amount. We refer readers to section IV.B. of the preamble of this proposed rule for a complete discussion on the FY 2021 inpatient hospital update to the standardized amount. We also refer readers to the previous table for the four possible applicable percentage increases that would be applied to update the national standardized amount. The proposed standardized amounts shown in Tables 1A through 1C that are published in section VI. of this Addendum and that are available via the internet on the CMS website reflect these differential amounts.

Although the update factors for FY 2021 are set by law, we are required by section 1886(e)(4) of the Act to recommend, taking into account MedPAC's recommendations, appropriate update factors for FY 2021 for both IPPS hospitals and hospitals and hospital units excluded from the IPPS. Section 1886(e)(5)(A) of the Act requires that we publish our recommendations in the **Federal Register** for public comment. Our recommendation on the update factors is set forth in Appendix B of this proposed rule.

4. Methodology for Calculation of the Average Standardized Amount

The methodology we used to calculate the proposed FY 2021 standardized amount is as follows:

• To ensure we are only including hospitals paid under the IPPS in the calculation of the standardized amount, we applied the following inclusion and exclusion criteria: Include hospitals whose last four digits fall between 0001 and 0879 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); exclude CAHs at the time of this proposed rule; exclude hospitals in Maryland (because these hospitals are paid under an all payer model under section 1115A of the Act); and remove PPS-excluded cancer hospitals that have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.

• As in the past, we are proposing to adjust the FY 2021 standardized amount to remove the effects of the FY 2020 geographic reclassifications and outlier payments before applying the FY 2021 updates. We then applied budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on proposed FY 2021 payment policies.

• We do not remove the prior year's budget neutrality adjustments for reclassification and recalibration of the DRG relative weights and for updated wage data because, in accordance with sections 1886(d)(4)(C)(iii) and 1886(d)(3)(E) of the Act, estimated aggregate payments after updates in the DRG relative weights and wage index should equal estimated aggregate payments prior to the changes. If we removed the prior year's adjustment, we would not satisfy these conditions.

Budget neutrality is determined by comparing aggregate IPPS payments before and after making changes that are required to be budget neutral (for example, changes to MS–DRG classifications, recalibration of the MS–DRG relative weights, updates to the wage index, and different geographic reclassifications). We include outlier payments in the simulations because they may be affected by changes in these parameters.

• Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50433), because IME Medicare Advantage payments are made to IPPS hospitals under section 1886(d) of the Act, we believe these payments must be part of these budget neutrality calculations. However, we note that it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation or the outlier offset to the standardized amount because the statute requires that outlier payments be not less than 5 percent nor more than 6 percent of total ''operating DRG payments,'' which does not include IME and DSH payments. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.

• Consistent with the methodology in the FY 2012 IPPS/LTCH PPS final rule, in order to ensure that we capture only fee-for-service claims, we are only including claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).

• Consistent with our methodology established in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57277), in order to further ensure that we capture only FFS claims, we are excluding claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).

• Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50423), we examine the MedPAR file and remove pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field for the budget neutrality adjustments. We also remove organ acquisition charges from the covered charge field for the budget neutrality adjustments because organ acquisition is a pass-through payment not paid under the IPPS.

• The participation of hospitals under the BPCI (Bundled Payments for Care Improvement) Advanced model started on October 1, 2018. The BPCI Advanced model, tested under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), is comprised of a single payment and risk track, which bundles payments for multiple services beneficiaries receive during a Clinical Episode. Acute care hospitals may participate in the BPCI Advanced model in one of two capacities: As a model Participant or as a downstream Episode Initiator. Regardless of the capacity in which they participate in the BPCI Advanced model, participating acute care hospitals will continue to receive IPPS payments under section 1886(d) of the Act. Acute care hospitals that are Participants also assume financial and quality performance accountability for Clinical Episodes in the form of a reconciliation payment. For additional information on the BPCI Advanced model, we refer readers to the BPCI Advanced web page on the CMS Center for Medicare and Medicaid Innovation's website at: *https://innovation.cms.gov/initiatives/bpci-advanced/*.

For FY 2021, consistent with how we treated hospitals that participated in the BPCI Advanced Model in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42620), we are proposing to include all applicable data from subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations. We believe it is appropriate to include all applicable data from the subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations because these hospitals are still receiving IPPS payments under section 1886(d) of the Act. For the same reasons, we also are proposing to include all applicable data from subsection (d) hospitals participating in the Comprehensive Care for Joint Replacement (CJR) Model in our IPPS payment modeling and ratesetting calculations.

• Consistent with our methodology established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688), we believe that it is appropriate to include adjustments for the Hospital Readmissions Reduction Program and the Hospital VBP Program (established under the Affordable Care Act) within our budget neutrality calculations.

Both the hospital readmissions payment adjustment (reduction) and the hospital VBP payment adjustment (redistribution) are applied on a claim-by-claim basis by adjusting, as applicable, the base-operating DRG payment amount for individual subsection (d) hospitals, which affects the overall sum of aggregate payments on each side of the comparison within the budget neutrality calculations.

In order to properly determine aggregate payments on each side of the comparison, consistent with the approach we have taken in prior years, for FY 2021, we are proposing to apply a proposed proxy based on the prior fiscal year hospital readmissions payment adjustment (for FY 2021 this would be FY 2020 final adjustment factors from Table 15 of the FY 2020 IPPS/LTCH final rule) and a proposed proxy based on the prior fiscal year hospital VBP payment adjustment (for FY 2021 this would be FY 2020 final adjustment factors from Table 16B of the FY 2020 IPPS/LTCH final rule) on each side of the comparison, consistent with the methodology that we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688). That is, we are proposing to apply a proxy readmissions payment adjustment factor and a proxy hospital VBP payment adjustment factor from the prior final rule on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

• The Affordable Care Act also established section 1886(r) of the Act, which modifies the methodology for computing the Medicare DSH payment adjustment beginning in FY 2014. Beginning in FY 2014, IPPS hospitals receiving Medicare DSH payment adjustments receive an empirically justified Medicare DSH payment equal to 25 percent of the amount that would previously have been received under the statutory formula set forth under section 1886(d)(5)(F) of the Act governing the Medicare DSH payment adjustment. In accordance with section 1886(r)(2) of the Act, the remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured and any additional statutory adjustment, will be available to make additional payments to Medicare DSH hospitals based on their share of the total amount of uncompensated care reported by Medicare DSH hospitals for a given time period. In order to properly determine aggregate payments on each side of the comparison for budget neutrality, prior to FY 2014, we included estimated Medicare DSH payments on both sides of our comparison of

aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

To do this for FY 2021 (as we did for the last 7 fiscal years), we are proposing to include estimated empirically justified Medicare DSH payments that will be paid in accordance with section 1886(r)(1) of the Act and estimates of the additional uncompensated care payments made to hospitals receiving Medicare DSH payment adjustments as described by section 1886(r)(2) of the Act. That is, we are proposing to consider estimated empirically justified Medicare DSH payments at 25 percent of what would otherwise have been paid, and also the estimated additional uncompensated care payments for hospitals receiving Medicare DSH payment adjustments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

- When calculating total payments for budget neutrality, to determine total payments for SCHs, we model total hospital-specific rate payments and total Federal rate payments and then include whichever one of the total payments is greater. As discussed in section IV.G. of the preamble to this proposed rule and later in this section, we are proposing to continue to use the FY 2014 finalized methodology under which we take into consideration uncompensated care payments in the comparison of payments under the Federal rate and the hospital-specific rate for SCHs. Therefore, we are proposing to include estimated uncompensated care payments in this comparison.

Similarly, for MDHs, as discussed in section IV.G. of the preamble of this proposed rule, when computing payments under the Federal national rate plus 75 percent of the difference between the payments under the Federal national rate and the payments under the updated hospital-specific rate, we are proposing to continue to take into consideration uncompensated care payments in the computation of payments under the Federal rate and the hospital-specific rate for MDHs.

- We are proposing to include an adjustment to the standardized amount for those hospitals that are not meaningful EHR users in our modeling of aggregate payments for budget neutrality for FY 2021. Similar to FY 2020, we are including this adjustment based on data on the prior year's performance. Payments for hospitals will be estimated based on the proposed applicable standardized amount in Tables 1A and 1B for discharges occurring in FY 2021.
- In our determination of all proposed budget neutrality factors described in section II.A.4. of this Addendum, we use transfer-adjusted discharges. Specifically, we calculated the transfer-adjusted discharges using the statutory expansion of the postacute care transfer policy to include discharges to hospice care by a hospice program as discussed in section IV.A.2.b. of the preamble of this proposed rule.

We finally note that the wage index value is calculated and assigned to a hospital based on the hospital's labor market area. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on the Core-Based Statistical Areas (CBSAs) established by the Office of Management and Budget (OMB). The current statistical areas used in FY 2020 are based on OMB standards published on February 28, 2013 (79 FR 49951) and Census 2010 data and Census Bureau population estimates for 2014 and 2015 (OMB Bulletin No. 17–01). As stated in section II.D.2. of the preamble to this proposed rule, 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. 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 OMB Bulletin No. 18–04 may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf*. (We note, 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*), and as discussed in preamble, this bulletin was not issued in time for development of this proposed rule.)

In section III.A.2. of the preamble to this proposed rule, we are proposing to implement the revised OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, effective October 1, 2020 beginning with the FY 2021 IPPS wage index. Consistent with our proposed policy to adopt the revised OMB delineations, in order to properly determine aggregate payments on each side of the comparison for our budget neutrality calculations, we are using wage indexes based on the new OMB delineations in the determination of all of the budget neutrality factors discussed in this section. We also note that, consistent with past practice as finalized in the FY 2005 IPPS final rule (69 FR 49034), we are not proposing to adopt the revised OMB delineations themselves in a budget neutral manner. We continue to believe that the proposed revision to the labor market areas in and of itself does not constitute an ''adjustment or update'' to the adjustment for area wage differences, as provided under section 1886(d)(3)(E) of the Act.

a. Proposed Recalibration of MS–DRG Relative Weights

Section 1886(d)(4)(C)(iii) of the Act specifies that, beginning in FY 1991, the annual DRG reclassification and recalibration of the relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. As discussed in section II.G. of the preamble of this proposed rule, we normalized the recalibrated MS–DRG relative weights by an adjustment factor so that the average case relative weight after recalibration is equal to the average case relative weight prior to recalibration. However, equating the average case relative weight after recalibration to the average case relative weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals because payments to hospitals are affected by factors other than average case relative weight. Therefore, as we have done in past years, we are proposing to make a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

For FY 2021, to comply with the requirement that MS–DRG reclassification and recalibration of the relative weights be budget neutral for the standardized amount and the hospital-specific rates, we used FY 2019 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2020 labor-related share percentages, the revised OMB labor market area delineations proposed for FY 2021, the FY 2020 relative weights, and the FY 2020 pre-reclassified wage data, and applied the proposed FY 2021 hospital readmissions payment adjustments and estimated FY 2021 hospital VBP payment adjustments; and
- Aggregate payments using the FY 2020 labor-related share percentages, the revised OMB labor market area delineations proposed for FY 2021, the proposed FY 2021 relative weights, and the FY 2020 pre-reclassified wage data, and applied the proposed FY 2021 hospital readmissions payment adjustments and estimated FY 2021 hospital VBP payment adjustments applied previously. Because this payment simulation uses the FY 2021 relative weights, consistent with our proposal in section IV.I. of the preamble to this proposed rule, we applied the proposed adjustor for CAR T-cell therapy clinical trial cases in our simulation of these payments. (As discussed in section II.E.2.b. of the preamble of this proposed rule, we also proposed to calculate an adjustment to account for the CAR T-cell therapy cases identified as clinical trial cases in calculating the FY 2021 relative weights and for purposes of budget neutrality and outlier simulations.) We note that because the simulations of payments for all of the budget neutrality factors discussed in this section also use the FY 2021 relative weights, we also applied the proposed adjustor for CAR T-cell therapy clinical trial cases in all simulations of payments for the budget neutrality factors discussed later in this section. We refer the reader to section IV.I. of the preamble of this proposed rule for a complete discussion on the proposed adjustor for CAR T-cell therapy clinical trial cases and to section II.E.2.b. of the preamble of this proposed rule, for a complete discussion of the proposed adjustment to the FY 2021 relative weights to account for the CAR T-cell therapy cases identified as clinical trial cases.

Based on this comparison, we computed a proposed budget neutrality adjustment factor and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, we also are proposing to apply the MS–DRG reclassification and recalibration budget neutrality factor to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2020. Please see the table later in this section setting forth each of the FY 2021 proposed budget neutrality factors.

b. Updated Wage Index—Proposed Budget Neutrality Adjustment

Section 1886(d)(3)(E)(i) of the Act requires us to update the hospital wage index on an annual basis beginning October 1, 1993. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. Section 1886(d)(3)(E)(i) of the Act requires that we implement the wage index adjustment in a budget neutral manner. However, section 1886(d)(3)(E)(ii) of the Act sets the labor-related share at 62 percent for hospitals with a wage index less than or equal to 1.0000, and section 1886(d)(3)(E)(i) of the Act provides that the Secretary shall calculate the budget neutrality adjustment for the adjustments or updates made under that provision as if section 1886(d)(3)(E)(ii) of the Act had not been enacted. In other words, this section of the statute requires that we implement the updates to the wage index in a budget neutral manner, but that our budget neutrality adjustment should not take into account the requirement that we set the labor-related share for hospitals with wage indexes less than or equal to 1.0000 at the more advantageous level of 62 percent. Therefore, for purposes of this budget neutrality adjustment, section 1886(d)(3)(E)(i) of the Act prohibits us from taking into account the fact that hospitals with a wage index less than or equal to 1.0000 are paid using a labor-related share of 62 percent. Consistent with current policy, for FY 2021, we are proposing to adjust 100 percent of the wage index factor for occupational mix. We describe the occupational mix adjustment in section III.E. of the preamble of this proposed rule.

To compute a proposed budget neutrality adjustment factor for wage index and labor-related share percentage changes, we used FY 2019 discharge data to simulate payments and compared the following:

- Aggregate payments using the revised OMB labor market area delineations proposed for FY 2021, the proposed FY 2021 relative weights and the FY 2020 pre-reclassified wage indexes, applied the FY 2020 labor-related share of 68.3 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the proposed FY 2021 hospital readmissions payment adjustment and the estimated FY 2021 hospital VBP payment adjustment; and
- Aggregate payments using the revised OMB labor market area delineations proposed for FY 2021, the proposed FY 2021 relative weights and the proposed FY 2021 pre-reclassified wage indexes, applied the proposed labor-related share for FY 2021 of 68.3 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the same proposed FY 2021 hospital readmissions payment adjustments and estimated FY 2021 hospital VBP payment adjustments applied previously.

In addition, we applied the proposed MS–DRG reclassification and recalibration budget neutrality adjustment factor (derived in the first step) to the proposed payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2020 to FY 2021. Based on this comparison, we computed a proposed budget neutrality adjustment factor and applied this factor to the standardized amount for changes to the wage index. Please see the table later in this section for a summary of the FY 2021 proposed budget neutrality factors.

c. Reclassified Hospitals—Proposed Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that certain rural hospitals are deemed urban. In addition, section 1886(d)(10) of the Act provides for the reclassification of hospitals based on determinations by the MGCRB. Under section 1886(d)(10) of the Act, a hospital may be reclassified for purposes of the wage index.

Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amount to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. We note, with regard to the requirement under section 1886(d)(8)(C)(iii) of the Act, as finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42333 through 42336), we excluded the wage data of urban hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act (as implemented in § 412.103) from the calculation of ''the wage index for rural areas in the State in which the county is located.'' We refer the reader to the FY 2015 IPPS final rule (79 FR 50371 and 50372) for a complete discussion regarding the requirement of section 1886(d)(8)(C)(iii) of the Act. We further note that the wage index adjustments provided for under section 1886(d)(13) of the Act are not budget neutral. Section 1886(d)(13)(H) of the Act provides that any increase in a wage index under section 1886(d)(13) shall not be taken into account in applying any budget neutrality adjustment with respect to such index under section 1886(d)(8)(D) of the Act. To calculate the budget neutrality adjustment factor for FY 2021, we used FY 2019 discharge data to simulate payments and compared the following:

- Aggregate payments using the proposed FY 2021 labor-related share percentages, the revised OMB labor market area delineations proposed for FY 2021, the proposed FY 2021 relative weights, and the proposed FY 2021 wage data prior to any reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, and applied the proposed FY 2021 hospital readmissions payment adjustments and the estimated FY 2021 hospital VBP payment adjustments; and
- Aggregate payments using the proposed FY 2021 labor-related share percentages, the revised OMB labor market area delineations proposed for FY 2021, the proposed FY 2021 relative weights, and the proposed FY 2021 wage data after such reclassifications, and applied the same proposed FY 2021 hospital readmissions payment adjustments and the estimated FY 2021 hospital VBP payment adjustments applied previously.

We note that the reclassifications applied under the second simulation and comparison are those listed in Table 2 associated with this proposed rule, which is available via the internet on the CMS website. This table reflects reclassification crosswalks proposed for FY 2021, and apply the proposed policies explained in section III. of the preamble of this proposed rule. Based on this comparison, we computed a proposed budget neutrality adjustment factor and applied this factor to the standardized amount to ensure that the effects of these provisions are budget neutral, consistent with the statute. Please see the table later in this section for a summary of the FY 2021 proposed budget neutrality factors.

The proposed FY 2021 budget neutrality adjustment factor was applied to the proposed standardized amount after removing the effects of the FY 2020 budget neutrality adjustment factor. We note that the proposed FY 2021 budget neutrality adjustment reflects FY 2021 wage index reclassifications approved by the MGCRB or the Administrator at the time of development of this proposed rule.

d. Rural Floor—Proposed Budget Neutrality Adjustment

Under § 412.64(e)(4), we make an adjustment to the wage index to ensure that aggregate payments after implementation of the rural floor under section 4410 of the BBA (Pub. L. 105–33) is equal to the aggregate prospective payments that would have been made in the absence of this provision. Consistent with section 3141 of the Affordable Care Act and as discussed in section III.G. of the preamble of this proposed rule and codified at § 412.64(e)(4)(ii), the budget neutrality adjustment for the rural floor is a national adjustment to the wage index. We note, as finalized in the FY 2020 IPPS/LTCH final rule (84 FR 42332 through 42336), for FY 2021 we are calculating the rural floor without including the wage data of urban hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act (as implemented in § 412.103).

Similar to our calculation in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50369 through 50370), for FY 2021, we are proposing to calculate a national rural Puerto Rico wage index. Because there are no rural Puerto Rico hospitals with established wage data, our calculation of the proposed FY 2021 rural Puerto Rico wage index is based on the policy adopted in the FY 2008 IPPS final rule with comment period (72 FR 47323). That is, we use the unweighted average of the wage indexes from all CBSAs (urban areas) that are contiguous (share a border with) to the rural counties to compute the rural floor (72 FR 47323; 76 FR 51594). Under the OMB labor market area delineations, except for Arecibo, Puerto Rico (CBSA 11640), all other Puerto Rico urban areas are contiguous to a rural area. Therefore, based on our existing policy, the proposed FY 2021 rural Puerto Rico wage index is calculated based on the average of the proposed FY 2021 wage indexes for the following urban areas: Aguadilla-Isabela, PR (CBSA 10380); Guayama, PR (CBSA 25020); Mayaguez, PR (CBSA 32420); Ponce, PR (CBSA 38660); San German, PR (CBSA

41900); and San Juan-Carolina-Caguas, PR (CBSA 41980).

To calculate the proposed national rural floor budget neutrality adjustment factor, we used FY 2019 discharge data to simulate payments, the revised OMB labor market area delineations proposed for FY 2021 and the proposed post-reclassified national wage indexes and compared the following:

- National simulated payments without the proposed national rural floor; and
- National simulated payments with the proposed national rural floor.

Based on this comparison, we determined a proposed national rural floor budget neutrality adjustment factor. The national adjustment was applied to the national wage indexes to produce proposed rural floor budget neutral wage indexes. Please see the table later in this section for a summary of the FY 2021 proposed budget neutrality factors.

e. Proposed Rural Community Hospital Demonstration Program Adjustment

In section IV.O. of the preamble of this proposed rule, we discuss the Rural Community Hospital Demonstration program, which was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148). Subsequently, section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted December 13, 2016, amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act, as further discussed later in this section). We make an adjustment to the standardized amount to ensure the effects of the Rural Community Hospital Demonstration program are budget neutral as required under section 410A(c)(2) of Public Law 108–173. We refer readers to section IV.O. of the preamble of this proposed rule for complete details regarding the Rural Community Hospital Demonstration.

With regard to budget neutrality, as mentioned earlier, we make an adjustment to the standardized amount to ensure the effects of the Rural Community Hospital Demonstration are budget neutral, as required under section 410A(c)(2) of Public Law 108–173. For FY 2021, the total amount that we are proposing to apply to make an adjustment to the standardized amounts to ensure the effects of the Rural Community Hospital Demonstration program are budget neutral is $40,804,704. Accordingly, using the most recent data available to account for the estimated costs of the demonstration program, for FY 2021, we computed a proposed factor for the Rural Community Hospital Demonstration budget neutrality adjustment that will be applied to the standardized amount. Please see the table later in this section for a summary of the FY 2021 proposed budget neutrality factors. We refer readers to section IV.O. of the preamble of this proposed rule on complete details regarding the calculation of the amount we are applying to make an adjustment to the standardized amounts.

We note that, as discussed in section IV.O. of the preamble of this proposed rule, if updated or additional data become available prior to issuance of the FY 2021 IPPS/LTCH PPS final rule, we would use those data to the extent appropriate to determine the budget neutrality offset amount for FY 2021. We refer readers to section IV.O. of the preamble of this proposed rule on complete details regarding the availability of additional data prior to the FY 2021 IPPS/LTCH PPS final rule.

f. Proposed Stem Cell Acquisition Reasonable Cost Based Payment Budget Neutrality Adjustment

In section IV.H. of the preamble of this proposed rule, we discuss the reasonable cost based payment for allogeneic hematopoietic stem cell acquisition costs beginning in FY 2021. Section 108 of the Further Consolidated Appropriations Act, 2020 requires that, for cost reporting periods beginning on or after October 1, 2020, in the case of a subsection (d) hospital that furnishes an allogeneic hematopoietic stem cell transplant, payment to such hospital for hematopoietic stem cell acquisition shall be made on a reasonable cost basis, and also requires that, beginning in FY 2021, the payments made based on reasonable cost for the acquisition costs of allogeneic hematopoietic stem cells be made in a budget neutral manner. That is, under section 1886(d)(4)(C)(iii) of the Act as amended by section 108 of the Further Consolidated Appropriations Act, 2020, beginning with FY 2021, the reasonable cost based payments for allogeneic hematopoietic stem cell acquisition costs are to be made in a manner that assures that the aggregate IPPS payments for discharges in the fiscal year are not greater or less than those that would have been made without such payments. With regard to budget neutrality, we are proposing to make an adjustment to the standardized amount to ensure the effects of the reasonable cost-based payments for allogeneic hematopoietic stem cell acquisition costs are budget neutral, as required under section 1886(d)(4)(C)(iii) of the Act as amended by section 108 of Public Law 116–94. For FY 2021, based on the most recent data available for this proposed rule, the total amount that we are proposing to apply to make an adjustment to the standardized amounts to ensure that the reasonable cost based payments for allogeneic hematopoietic stem cell acquisition costs are budget neutral is $15,865,374. Accordingly, for FY 2021 we computed a proposed budget neutrality adjustment that we are proposing to apply to the standardized amounts for FY 2021. Please see the table later in this section setting forth each of the FY 2021 proposed budget neutrality factors. We refer readers to section IV.H. of the preamble of this proposed rule for further details regarding the calculation of the estimated amount of reasonable cost based payments for allogeneic hematopoietic stem cell acquisition costs that we are proposing to use to make an adjustment to the standardized amount for FY 2021.

g. Continuation of the Low Wage Index Hospital Policy—Proposed Budget Neutrality Adjustment

As discussed in section III.N. of the preamble of this proposed rule, we are continuing the wage index policy finalized in the FY 2020 IPPS/LTCH PPS final rule to address wage index disparities by increasing the wage index values for hospitals with a wage index value below the 25th percentile wage index value across all hospitals (the low wage index hospital policy). As discussed in the FY 2020 IPPS/LTCH final rule (84 FR 42332), consistent with our current methodology for implementing wage index budget neutrality under section 1886(d)(3)(E) of the Act, we are making a budget neutrality adjustment to the national standardized amount for all hospitals so that the increase in the wage index for hospitals with a wage index below the 25th percentile wage index, is implemented in a budget neutral manner.

To calculate this proposed budget neutrality adjustment factor for FY 2021, we used FY 2019 discharge data to simulate payments and compared the following:

- Aggregate payments using the proposed FY 2021 labor-related share percentages, the revised OMB labor market area delineations proposed for FY 2021, the proposed FY 2021 relative weights, and the proposed FY 2021 wage index for each hospital before adjusting the wage indexes under the low wage index hospital policy but without the 5 percent cap, and applied the proposed FY 2021 hospital readmissions payment adjustments and the estimated FY 2021 hospital VBP payment adjustments, and the operating outlier reconciliation adjusted outlier percentage discussed later in this section; and
- Aggregate payments using the FY 2021 labor-related share percentages, the revised OMB labor market area delineations proposed for FY 2021, the FY 2021 relative weights, and the FY 2021 wage index for each hospital after adjusting the wage indexes under the low wage index hospital policy but without the 5 percent cap, and applied the same proposed FY 2021 hospital readmissions payment adjustments and the estimated FY 2021 hospital VBP payment adjustments applied previously, and the operating outlier reconciliation adjusted outlier percentage discussed later in this section.

This proposed FY 2021 budget neutrality adjustment factor was applied to the standardized amount. Please see the table later in this section setting forth each of the FY 2021 proposed budget neutrality factors.

h. Proposed Transition Budget Neutrality Adjustment

As noted above, in section III.A.2. of the preamble to this proposed rule, we are proposing to implement the revised OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, effective October 1, 2020 beginning with the FY 2021 IPPS wage index. We stated that while the revised OMB delineations in the OMB bulletin (OMB Bulletin 18–04) are not based on new census data, there were some material changes in the OMB delineations. In accordance with our past practice of

implementing transition policies to help mitigate negative impacts on hospitals of certain wage index proposals, we believe that if we adopt the proposed revised OMB delineations, it would be appropriate to implement a transition policy since, as mentioned above, some of these revisions are material, and may negatively impact payments to hospitals. We stated that we believe applying a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index from the prior fiscal year, as we did for FY 2020, would be an appropriate transition for FY 2021 for the revised OMB delineations. We refer the reader to section III.A.2. of the preamble to this proposed rule for a complete discussion on the rationale of this transition.

For FY 2020, we are proposing to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to apply a budget neutrality adjustment to the standardized amount so that our transition for hospitals negatively impacted is implemented in a budget neutral manner. We refer readers to section III.A.2. of the preamble of this proposed rule for a complete discussion regarding this proposed policy. To calculate a proposed transition budget neutrality adjustment factor for FY 2021, we used FY 2019 discharge data to simulate payments and compared the following:

- Aggregate payments without the proposed 5-percent cap using the proposed FY 2021 labor-related share percentages, the revised OMB labor market area delineations proposed for FY 2021, the proposed FY 2021 relative weights, the proposed FY 2021 wage index for each hospital after adjusting the wage indexes under the low wage index hospital policy with the associated budget neutrality adjustment to the standardized amount, and applied the proposed FY 2021 hospital readmissions payment adjustments and the estimated FY 2021 hospital VBP payment adjustments, and the proposed operating outlier reconciliation adjusted outlier percentage; and
- Aggregate payments with the proposed 5-percent cap using the proposed FY 2021 labor-related share percentages, the revised OMB labor market area delineations proposed for FY 2021, the proposed FY 2021 relative weights, the proposed FY 2021 wage index for each hospital after adjusting the wage indexes under the low wage index hospital policy with the associated budget neutrality adjustment to the standardized amount, and applied the same proposed FY 2021 hospital readmissions payment adjustments and the estimated FY 2021 hospital VBP payment adjustments applied previously, and the proposed operating outlier reconciliation adjusted outlier percentage.

This proposed FY 2021 budget neutrality adjustment factor was applied to the proposed standardized amount. Please see the table later in this section setting forth each of the FY 2021 proposed budget neutrality factors.

We note, Table 2 associated with this proposed rule, which is available via the internet on the CMS website contains the wage index by provider before and after applying the low wage index hospital policy and the proposed transition.

Summary of FY 2021 Proposed Budget Neutrality Factors	
MS-DRG Recalibration Budget Neutrality Factor	0.998761
Wage Index Budget Neutrality Factor	0.999362
Reclassification Budget Neutrality Factor	0.988003
*Rural Floor Budget Neutrality Factor	0.993991
Low Wage Index Hospital Policy Budget Neutrality Factor	0.998241
Transition Budget Neutrality Factor	0.998580
Rural Demonstration Budget Neutrality Factor	0.999642
Stem Cell Acquisition Budget Neutrality Factor	0.999861

*The rural floor budget neutrality factor is applied to the national wage indexes while the rest of the budget neutrality adjustments are applied to the standardized amounts.

i. Proposed Adjustment for FY 2021 Required Under Section 414 of Public Law 114–10 (MACRA)

As stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56785), once the recoupment required under section 631 of the ATRA was complete, we had anticipated making a single positive adjustment in FY 2018 to offset the reductions required to recoup the $11 billion under section 631 of the ATRA. However, section 414 of the MACRA (which was enacted on April 16, 2015) replaced the single positive adjustment we intended to make in FY 2018 with a 0.5 percent positive adjustment for each of FYs 2018 through 2023. (As noted in the FY 2018 IPPS/LTCH PPS proposed and final rules, section 15005 of the 21st Century Cures Act (Pub. L. 114–255), which was enacted December 13, 2016, reduced the adjustment for FY 2018 from 0.5 percentage points to 0.4588 percentage points.) Therefore, for FY 2021, we are proposing to implement the required +0.5 percent adjustment to the standardized amount. This is a permanent adjustment to the payment rates.

j. Proposed Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for ''outlier'' cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, any new technology add-on payments, and the ''outlier threshold'' or ''fixed-loss'' amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). We refer to the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, any new technology add-on payments, and the outlier threshold as the outlier ''fixed-loss cost threshold.'' To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's CCR is applied to the total covered charges for the case to convert the charges to estimated costs. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the estimated costs above the fixed-loss cost threshold. The marginal cost factor for FY 2021 is 80 percent, or 90 percent for burn MS–DRGs 927, 928, 929, 933, 934 and 935. We have used a marginal cost factor of 90 percent since FY 1989 (54 FR 36479 through 36480) for designated burn DRGs as well as a marginal cost factor of 80 percent for all other DRGs since FY 1995 (59 FR 45367).

In accordance with section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments (which does not include IME and DSH payments) plus outlier payments. When setting the outlier threshold, we compute the percent target by dividing the total operating outlier payments by the total operating DRG payments plus outlier payments. We do not include any other payments such as IME and DSH within the outlier target amount. Therefore, it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation. Section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amount by a factor to account for the estimated proportion of total DRG payments made to outlier cases. More information on outlier payments may be found on the CMS website at: *http://*

www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/outlier.htm.

(1) Proposed Methodology To Incorporate an Estimate of Outlier Reconciliation in the FY 2020 Outlier Fixed-Loss Cost Threshold

The regulations in 42 CFR 412.84(i)(4) state that any outlier reconciliation at cost report settlement will be based on operating and capital cost-to-charge ratios (CCRs) calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled. We have instructed MACs to identify for CMS any instances where: (1) A hospital's actual CCR for the cost reporting period fluctuates plus or minus 10 percentage points compared to the interim CCR used to calculate outlier payments when a bill is processed; and (2) the total outlier payments for the hospital exceeded $500,000.00 for that cost reporting period. If we determine that a hospital's outlier payments should be reconciled, we reconcile both operating and capital outlier payments. We refer readers to section 20.1.2.5 of Chapter 3 of the Medicare Claims Processing Manual (available on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*) for complete details regarding outlier reconciliation. The regulation at § 412.84(m) further states that at the time of any outlier reconciliation under § 412.84(i)(4), outlier payments may be adjusted to account for the time value of any underpayments or overpayments. Section 20.1.2.6 of Chapter 3 of the Medicare Claims Processing Manual contains instructions on how to assess the time value of money for reconciled outlier amounts.

If the operating CCR of a hospital subject to outlier reconciliation is lower at cost report settlement compared to the operating CCR used for payment, the hospital will owe CMS money because it received an outlier overpayment at the time of claim payment. Conversely, if the operating CCR increases at cost report settlement compared to the operating CCR used for payment, CMS will owe the hospital money because the hospital outlier payments were underpaid.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42625), for FY 2021, we finalized a methodology to incorporate outlier reconciliation in the FY 2021 outlier fixed loss cost threshold. As discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19592), we stated that rather than trying to predict which claims and/or hospitals may be subject to outlier reconciliation, we believe a methodology that incorporates an estimate of outlier reconciliation dollars based on actual outlier reconciliation amounts reported in historical cost reports would be a more feasible approach and provide a better estimate and predictor of outlier reconciliation for the upcoming fiscal year. We also stated that we believe the methodology addresses stakeholder's concerns on the impact of outlier reconciliation on the modeling of the outlier threshold. For a detailed discussion of additional background regarding outlier reconciliation, we refer the reader to the FY 2020 IPPS/LTCH PPS final rule.

(a) Incorporating a Proposed Projection of Outlier Payment Reconciliations for the FY 2021 Outlier Threshold Calculation

Based on the methodology finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42625), for FY 2021, we are proposing to continue to incorporate outlier reconciliation in the FY 2021 outlier fixed loss cost threshold.

As discussed in the FY 2020 IPPS/LTCH PPS final rule, for FY 2020, we used the historical outlier reconciliation amounts from the FY 2014 cost reports (cost reports with a begin date on or after October 1, 2013, and on or before September 30, 2014), which we believed would provide the most recent and complete available data to project the estimate of outlier reconciliation. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42625) for a complete discussion on the use of the FY 2014 cost report data for purposes of projecting outlier payment reconciliations for the FY 2020 outlier threshold calculation.

In the FY 2020 IPPS/LTCH PPS final rule, we stated that the methodology for FY 2020 could advance by 1 year the cost reports used to determine the historical outlier reconciliation. In this proposed rule, to determine a projection of outlier payment reconciliations for the FY 2021 outlier threshold calculation, we are proposing to advance the methodology by 1 year and use FY 2015 cost reports (cost reports with a begin date on or after October 1, 2014, and on or before September 30, 2015).

For FY 2021, we are proposing to use the same methodology from FY 2020 to incorporate a projection of operating outlier payment reconciliations for the FY 2021 outlier threshold calculation. The following steps are the same as those finalized in the FY 2020 final rule but with updated data for FY 2021:

Step 1.—Use the Federal FY 2015 cost reports for hospitals paid under the IPPS from the most recent publicly available quarterly HCRIS extract available at the time of development of the proposed and final rules, and exclude sole community hospitals (SCHs) that were paid under their hospital-specific rate (that is, if Worksheet E, Part A, Line 48 is greater than Line 47). We note that when there are multiple columns available for the lines of the cost report described in the following steps and the provider was paid under the IPPS for that period(s) of the cost report, then we believe it is appropriate to use multiple columns to fully represent the relevant IPPS payment amounts, consistent with our methodology for the FY 2020 final rule.

Step 2.—Calculate the aggregate amount of historical total of operating outlier reconciliation dollars (Worksheet E, Part A, Line 2.01) using the Federal FY 2015 cost reports from Step 1.

Step 3.—Calculate the aggregate amount of total Federal operating payments using the Federal FY 2015 cost reports from Step 1. The total Federal operating payments consist of the Federal payments (Worksheet E, Part A, Line 1.01 and Line 1.02, plus Line 1.03 and Line 1.04), outlier payments (Worksheet E, Part A, Line 2 and Line 2.02), and the outlier reconciliation payments (Worksheet E, Part A, Line 2.01). We note that a negative amount on Worksheet E, Part A, Line 2.01 for outlier reconciliation indicates an amount that was owed by the hospital, and a positive amount indicates this amount was paid to the hospital.

Step 4.—Divide the amount from Step 2 by the amount from Step 3 and multiply the resulting amount by 100 to produce the percentage of total operating outlier reconciliation dollars to total Federal operating payments for FY 2015. This percentage amount would be used to adjust the outlier target for FY 2021 as described in Step 5.

Step 5.—Because the outlier reconciliation dollars are only available on the cost reports, and not in the Medicare claims data in the MedPAR file used to model the outlier threshold, we are proposing to target 5.1 percent minus the percentage determined in Step 4 in determining the outlier threshold. Using the FY 2015 cost reports based on the December 2019 HCRIS extract, because the aggregate outlier reconciliation dollars from Step 2 are negative, but the percentage determined in Step 4 rounds to 0, we are targeting 5.1 percent for outlier payments for FY 2021 under our proposed methodology.

For this FY 2021 proposed rule, we used the December 2019 HCRIS extract of the cost report data to calculate the proposed percentage adjustment for outlier reconciliation. For the FY 2021 final rule, we are proposing to use the latest quarterly HCRIS extract that is publically available at the time of the development of that rule which, for FY 2021, would be the March 2020 extract. Similar to the FY 2020 final rule, we may also consider the use of more recent data that may become available for purpose of projecting the estimate of operating outlier reconciliation used in the calculation of the final FY 2021 outlier threshold.

For this FY 2021 proposed rule, based on the December 2019 HCRIS, 16 hospitals had an outlier reconciliation amount recorded on Worksheet E, Part A, Line 2.01 for total operating outlier reconciliation dollars of negative $2,516,904 (Step 2). The total Federal operating payments based on the December 2019 HCRIS was $90,313,815,275 (Step 3). The ratio (Step 4) is a negative 0.002787 percent, which, when rounded to the second digit, is 0.00 percent. Therefore, for FY 2021, we are proposing to incorporate a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.10 percent [5.1 percent-(- .00 percent)]. When the percentage of operating outlier reconciliation dollars to total Federal operating payments rounds to a negative value (that is, when the aggregate amount of outlier reconciliation as a percent of total operating payments rounds to a negative percent), the effect is a decrease to the outlier threshold compared to an outlier threshold that is calculated without including this estimate of operating outlier reconciliation dollars. In section II.A.4.i.(2). of this Addendum, we provide the FY 2021 outlier threshold as calculated for this proposed rule both with and without including this proposed percentage estimate of operating outlier reconciliation. However, we note that

for this proposed rule, the outlier threshold is the same with and without the proposed percentage estimate, since the projection of outlier reconciliation rounds to zero.

As explained in the FY 2020 IPPS/LTCH PPS final rule, we would continue to use a 5.1 percent target (or an outlier offset factor of 0.949) in calculating the outlier offset to the standardized amount. In the past, the outlier offset was six decimals because we targeted and set the threshold at 5.1 percent by adjusting the standardized amount by the outlier offset until operating outlier payments divided by total operating Federal payments plus operating outlier payments equaled approximately 5.1 percent (this approximation resulted in an offset beyond three decimals). However, under our proposed methodology, we believe a three decimal offset of 0.949 reflecting 5.1 percent is appropriate rather than the unrounded six decimal offset that we have calculated for prior fiscal years. Specifically, as discussed in section II.A.5. of this Addendum, we are proposing to determine an outlier adjustment by applying a factor to the standardized amount that accounts for the projected proportion of total estimated FY 2021 operating Federal payments paid as outliers. Our proposed modification to the outlier threshold methodology is designed to adjust the total estimated outlier payments for FY 2021 by incorporating the projection of negative outlier reconciliation. That is, under this proposal, total estimated outlier payments for FY 2021 would be the sum of the estimated FY 2021 outlier payments based on the claims data from the outlier model and the estimated FY 2021 total operating outlier reconciliation dollars. We believe the proposed methodology would more accurately estimate the outlier adjustment to the standardized amount by increasing the accuracy of the calculation of the total estimated FY 2021 operating Federal payments paid as outliers. In other words, the net effect of our outlier proposal to incorporate a projection for outlier reconciliation dollars into the threshold methodology would be that FY 2021 outlier payments (which include the estimated recoupment percentage for FY 2021 of 0.00 percent) would be 5.1 percent of total operating Federal payments plus total outlier payments. Therefore, the operating outlier offset to the standardized amount is 0.949 (1–0.051).

We are inviting public comment on our proposed methodology for projecting an estimate of outlier reconciliation and incorporating that estimate into the modeling for the fixed-loss cost outlier threshold for FY 2021.

(b) Proposed Reduction to the FY 2021 Capital Standard Federal Rate by an Adjustment Factor To Account for the Projected Proportion of Capital IPPS Payments Paid as Outliers

We establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital related costs (58 FR 46348). Similar to the calculation of the proposed adjustment to the standardized amount to account for the projected proportion of operating payments paid as outlier payments, as discussed in greater detail in section III.A.2. of this Addendum, we are proposing to reduce the FY 2021 capital standard Federal rate by an adjustment factor to account for the projected proportion of capital IPPS payments paid as outliers. The regulations in 42 CFR 412.84(i)(4) state that any outlier reconciliation at cost report settlement will be based on operating and capital CCRs calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled. As such, any reconciliation also applies to capital outlier payments.

For FY 2021, we are proposing to use the same methodology from FY 2020 to adjust the FY 2021 capital standard Federal rate by an adjustment factor to account for the projected proportion of capital IPPS payments paid as outliers. Similar to FY 2020, as part of our proposal for FY 2021 to incorporate into the outlier model the total outlier reconciliation dollars from the most recent and most complete fiscal year cost report data, we also are proposing to adjust our estimate of FY 2021 capital outlier payments to incorporate a projection of capital outlier reconciliation payments when determining the adjustment factor to be applied to the capital standard Federal rate to account for the projected proportion of capital IPPS payments paid as outliers. To do so, we are proposing to use the following methodology, which generally parallels the proposed methodology to incorporate a projection of operating outlier reconciliation payments for the FY 2021 outlier threshold calculation.

Step 1.—Use the Federal FY 2015 cost reports for hospitals paid under the IPPS from the most recent publicly available quarterly HCRIS extract available at the time of development of the proposed and final rules, and exclude SCHs that were paid under their hospital-specific rate (that is, if Worksheet E, Part A, Line 48 is greater than Line 47). We note that when there are multiple columns available for the lines of the cost report described in the following steps and the provider was paid under the IPPS for that period(s) of the cost report, then we believe it is appropriate to use multiple columns to fully represent the relevant IPPS payment amounts, consistent with our methodology for the FY 2020 final rule. We used the December 2019 HCRIS extract for this proposed rule and expect to use the March 2020 HCRIS extract for the FY 2021 final rule. Similar to the FY 2020 final rule, we may also consider the use of more recent data that may become available for purposes of projecting the estimate of capital outlier reconciliation used in the calculation of the final FY 2021 adjustment to the FY 2021 capital standard Federal rate.

Step 2.—Calculate the aggregate amount of the historical total of capital outlier reconciliation dollars (Worksheet E, Part A, Line 93, Column 1) using the Federal FY 2015 cost reports from Step 1.

Step 3.—Calculate the aggregate amount of total capital Federal payments using the Federal FY 2015 cost reports from Step 1. The total capital Federal payments consist of the capital DRG payments, including capital indirect medical education (IME) and capital disproportionate share hospital (DSH) payments (Worksheet E, Part A, Line 50, Column 1) and the capital outlier reconciliation payments (Worksheet E, Part A, Line 93, Column 1). We note that a negative amount on Worksheet E, Part A, Line 93 for capital outlier reconciliation indicates an amount that was owed by the hospital, and a positive amount indicates this amount was paid to the hospital.

Step 4.—Divide the amount from Step 2 by the amount from Step 3 and multiply the resulting amount by 100 to produce the percentage of total capital outlier reconciliation dollars to total capital Federal payments for FY 2015. This percentage amount would be used to adjust the estimate of capital outlier payments for FY 2021 as described in Step 5.

Step 5.—Because the outlier reconciliation dollars are only available on the cost reports, and not in the specific Medicare claims data in the MedPAR file used to estimate outlier payments, we are proposing that the estimate of capital outlier payments for FY 2021 would be determined by adding the percentage in Step 4 to the estimated percentage of capital outlier payments otherwise determined using the shared outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. (We note that this percentage is added for capital outlier payments but subtracted in the analogous step for operating outlier payments. We have a unified outlier payment methodology that uses a shared threshold to identify outlier cases for both operating and capital payments. The difference stems from the fact that operating outlier payments are determined by first setting a ''target'' percentage of operating outlier payments relative to aggregate operating payments which produces the outlier threshold. Once the shared threshold is set, it is used to estimate the percentage of capital outlier payments to total capital payments based on that threshold. Because the threshold is already set based on the operating target, rather than adjusting the threshold (or operating target), we adjust the percentage of capital outlier to total capital payments to account for the estimated effect of capital outlier reconciliation payments. This percentage is adjusted by adding the capital outlier reconciliation percentage from Step 4 to the estimate of the percentage of capital outlier payments to total capital payments based on the shared threshold.) Because the aggregate capital outlier reconciliation dollars from Step 2 are negative, the estimate of capital outlier payments for FY 2021 under our proposed methodology would be lower than the percentage of capital outlier payments otherwise determined using the shared outlier threshold.

Similarly, for this FY 2021 proposed rule, we used the December 2019 HCRIS extract of the cost report data to calculate the proposed percentage adjustment for outlier reconciliation. For the FY 2021 final rule, we are proposing to use the latest quarterly HCRIS extract that is publically available at the time of the development of that rule which, for FY 2021, would be the March

2020 extract. As previously noted, we may also consider the use of more recent data that may become available for purposes of projecting the estimate of capital outlier reconciliation used in the calculation of the final FY 2021 adjustment to the FY 2021 capital standard Federal rate.

For this FY 2021 proposed rule, the estimated percentage of FY 2021 capital outlier payments otherwise determined using the shared outlier threshold is 5.42 percent (estimated capital outlier payments of $432,102,494 divided by (estimated capital outlier payments of $432,102,494 plus the estimated total capital Federal payment of $7,569,294,589)). Based on the December 2019 HCRIS, 16 hospitals had an outlier reconciliation amount recorded on Worksheet E, Part A, Line 93 for total capital outlier reconciliation dollars of negative $956,065 (Step 2). The total Federal capital payments based on the December 2019 HCRIS was $8,114,838,772 (Step 3) which results in a ratio (Step 4) of −0.01 percent. Therefore, for FY 2021, taking into account projected capital outlier reconciliation payments under our proposed methodology would decrease the estimated percentage of FY 2021 aggregate capital outlier payments by 0.01 percent.

As discussed in section III.A.2. of this Addendum, we are proposing to incorporate the capital outlier reconciliation dollars from Step 5 when applying the outlier adjustment factor in determining the capital Federal rate based on the estimated percentage of capital outlier payments to total capital Federal rate payments for FY 2021.

We are inviting public comment on our proposed methodology for projecting an estimate of capital outlier reconciliation and incorporating that estimate into the modeling of the estimate of FY 2021 capital outlier payments for purposes of determining the capital outlier adjustment factor.

(2) Proposed FY 2021 Outlier Fixed-Loss Cost Threshold

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50977 through 50983), in response to public comments on the FY 2013 IPPS/LTCH PPS proposed rule, we made changes to our methodology for projecting the outlier fixed-loss cost threshold for FY 2014. We refer readers to the FY 2014 IPPS/LTCH PPS final rule for a detailed discussion of the changes.

As we have done in the past, to calculate the proposed FY 2021 outlier threshold, we simulated payments by applying proposed FY 2021 payment rates and policies using cases from the FY 2019 MedPAR file. We note that because this payment simulation uses the proposed FY 2021 relative weights, consistent with our proposal in section IV.I. of the preamble to this proposed rule, we applied the proposed adjustor for CAR–T cell therapy clinical trial cases in our simulation of these payments. As discussed in section II.E.2.b. of the preamble of this proposed rule, we also proposed to calculate an adjustment to account for the CAR T-cell therapy cases identified as clinical trial cases in calculating the FY 2021 relative weights and for purposes of budget neutrality and outlier simulations. As noted in section II.C. of this Addendum, we specify the formula used for actual claim payment which is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the PSF while CMS uses an adjusted CCR (as described later in this section) to project the threshold for the upcoming fiscal year. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier).

In order to determine the proposed FY 2021 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2019 to FY 2021. Consistent with the FY 2020 IPPS/LTCH PPS final rule (84 FR 42626 and 42627), we are proposing to use the following methodology to calculate the charge inflation factor for FY 2021:

- Include hospitals whose last four digits fall between 0001 and 0899 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); include CAHs that were IPPS hospitals for the time period of the MedPAR data being used to calculate the charge inflation factor; include hospitals in Maryland; and remove PPS-excluded cancer hospitals who have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.
- Include providers that are in both periods of charge data that are used to calculate the 1-year average annual rate-of-change in charges per case. We note this is consistent with the methodology used since FY 2014.
- We excluded Medicare Advantage IME claims for the reasons described in section I.A.4. of this Addendum. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.
- In order to ensure that we capture only FFS claims, we included claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).
- In order to further ensure that we capture only FFS claims, we excluded claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).
- We examined the MedPAR file and removed pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field. We also removed organ acquisition charges from the covered charge field because organ acquisition is a pass-through payment not paid under the IPPS.

Our general methodology to inflate the charges computes the 1-year average annual rate-of-change in charges per case which is then applied twice to inflate the charges on the MedPAR claims by 2 years (for example, FY 2019 to FY 2021).

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42627), we modified our charge inflation methodology. We stated that we believe balancing our preference to use the latest available data from the MedPAR files and stakeholders' concerns about being able to use publicly available MedPAR files to review the charge inflation factor can be achieved by modifying our methodology to use the publicly available Federal fiscal year period (that is, for FY 2020, we used the charge data from Federal fiscal years 2017 and 2018), rather than the most recent data available to CMS which, under our prior methodology, was based on calendar year data. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule for a complete discussion regarding this change. For the same reasons discussed in that rulemaking, for FY 2021, we are proposing to use the same methodology as FY 2020 and advance by 1 year the MedPAR data used to determine the charge inflation factor. That is, for FY 2021, we are proposing to use the MedPAR files for the two most recent available federal fiscal year time periods to calculate the charge inflation factor, as we did for FY 2020. Specifically, for this proposed rule we used the December 2018 MedPAR file of FY 2018 (October 1, 2017 to September 30, 2018) charge data (released for the FY 2020 IPPS/LTCH PPS proposed rule) and the December 2019 MedPAR file of FY 2019 (October 1, 2018 to September 30, 2019) charge data (released for this FY 2021 IPPS/LTCH PPS proposed rule) to compute the proposed charge inflation factor. We are proposing that for the FY 2021 final rule, we would use more recently updated data, that is the MedPAR files from March 2019 for the FY 2018 time period and March 2020 for the FY 2019 time period. Under this proposed methodology, to compute the 1-year average annual rate-of-change in charges per case for FY 2021, we compared the average covered charge per case of $61,533.34 ($582,022,123,240/9,458,647 cases) from October 1, 2017, through September 30, 2018 to the average covered charge per case of $65,442.49 ($601,183,502,371/9,186,440 cases) from October 1, 2018 through September 30, 2019. This rate-of-change was 6.4 percent (1.06353) or 13.1 percent (1.131096) over 2 years. The billed charges are obtained from the claim from the MedPAR file and inflated by the inflation factor specified previously.

As we have done in the past, in this FY 2021 IPPS/LTCH PPS proposed rule, we are proposing to establish the proposed FY 2021 outlier threshold using hospital CCRs from the December 2019 update to the Provider-Specific File (PSF)—the most recent available data at the time of the development of this proposed rule. We are proposing to apply the following edits to providers' CCRs in the PSF. We believe these edits are appropriate in order to accurately model the outlier threshold. We first search for Indian Health Service providers and those providers assigned the statewide average CCR from the current fiscal year. We then replace these CCRs with the statewide average CCR for the upcoming fiscal year. We also assign the statewide average CCR (for the upcoming fiscal year) to those providers that have no value in the CCR field in the PSF or whose CCRs exceed the ceilings described later in

this section (3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals). We do not apply the adjustment factors described later in this section to hospitals assigned the statewide average CCR. For FY 2021, we also are proposing to continue to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained later in this section). We also are proposing that, if more recent data become available, we would use that data to calculate the final FY 2021 outlier threshold.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we adopted a new methodology to adjust the CCRs. Specifically, we finalized a policy to compare the national average case-weighted operating and capital CCR from the most recent update of the PSF to the national average case-weighted operating and capital CCR from the same period of the prior year.

Therefore, as we have done since FY 2014, we are proposing to adjust the CCRs from the December 2019 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the December 2018 update of the PSF to the national average case-weighted operating CCR and capital CCR from the December 2019 update of the PSF. We note that we used total transfer-adjusted cases from FY 2019 to determine the national average case-weighted CCRs for both sides of the comparison. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we believe that it is appropriate to use the same case count on both sides of the comparison, because this will produce the true percentage change in the average case-weighted operating and capital CCR from 1 year to the next without any effect from a change in case count on different sides of the comparison.

Using this proposed methodology, for this proposed rule, we calculated a proposed December 2018 operating national average case-weighted CCR of 0.255979 and a proposed December 2019 operating national average case-weighted CCR of 0.249649. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the December 2018 operating national average case-weighted CCR from the December 2019 operating national average case-weighted CCR and then dividing the result by the December 2018 national operating average case-weighted CCR. This resulted in a proposed national operating CCR adjustment factor of 0.975271.

We used this same proposed methodology to adjust the capital CCRs. Specifically, we calculated a December 2018 capital national average case-weighted CCR of 0.021043 and a December 2019 capital national average case-weighted CCR of 0.020255. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the December 2018 capital national average case-weighted CCR from the December 2019 capital national average case-weighted CCR and then dividing the result by the December 2018 capital national average case-weighted CCR. This resulted in a proposed national capital CCR adjustment factor of 0.962553.

For purposes of estimating the proposed outlier threshold for FY 2021, we used a wage index that reflects the policies discussed in this proposed rule. This includes the proposed frontier State floor adjustments in accordance with section 10324(a) of the Affordable Care Act, the proposed out-migration adjustment as added by section 505 of Public Law 108–173, as well as incorporating the FY 2021 wage index adjustment for hospitals with a wage index value below the 25th percentile, where the increase in the wage index value for these hospitals would be equal to half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals. We also incorporated our proposal of the 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in FY 2020. If we did not take the aforementioned into account, our estimate of total FY 2021 payments would be too low, and, as a result, our proposed outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.1 percent of total payments (which includes outlier reconciliation).

As described in sections IV.K. and IV.L., respectively, of the preamble of this proposed rule, sections 1886(q) and 1886(o) of the Act establish the Hospital Readmissions Reduction Program and the Hospital VBP Program, respectively. We do not believe that it is appropriate to include the proposed hospital VBP payment adjustments and the hospital readmissions payment adjustments in the proposed outlier threshold calculation or the proposed outlier offset to the standardized amount. Specifically, consistent with our definition of the base operating DRG payment amount for the Hospital Readmissions Reduction Program under § 412.152 and the Hospital VBP Program under § 412.160, outlier payments under section 1886(d)(5)(A) of the Act are not affected by these payment adjustments. Therefore, outlier payments would continue to be calculated based on the unadjusted base DRG payment amount (as opposed to using the base-operating DRG payment amount adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment). Consequently, we are proposing to exclude the proposed hospital VBP payment adjustments and the estimated hospital readmissions payment adjustments from the calculation of the proposed outlier fixed-loss cost threshold.

We note that, to the extent section 1886(r) of the Act modifies the DSH payment methodology under section 1886(d)(5)(F) of the Act, the uncompensated care payment under section 1886(r)(2) of the Act, like the empirically justified Medicare DSH payment under section 1886(r)(1) of the Act, may be considered an amount payable under section 1886(d)(5)(F) of the Act such that it would be reasonable to include the payment in the outlier determination under section 1886(d)(5)(A) of the Act. As we have done since the implementation of uncompensated care payments in FY 2014, for FY 2021, we also are proposing to allocate an estimated per-discharge uncompensated care payment amount to all cases for the hospitals eligible to receive the uncompensated care payment amount in the calculation of the outlier fixed-loss cost threshold methodology. We continue to believe that allocating an eligible hospital's estimated uncompensated care payment to all cases equally in the calculation of the outlier fixed-loss cost threshold would best approximate the amount we would pay in uncompensated care payments during the year because, when we make claim payments to a hospital eligible for such payments, we would be making estimated per-discharge uncompensated care payments to all cases equally. Furthermore, we continue to believe that using the estimated per-claim uncompensated care payment amount to determine outlier estimates provides predictability as to the amount of uncompensated care payments included in the calculation of outlier payments. Therefore, consistent with the methodology used since FY 2014 to calculate the outlier fixed-loss cost threshold, for FY 2021, we are proposing to include estimated FY 2021 uncompensated care payments in the computation of the proposed outlier fixed-loss cost threshold. Specifically, we are proposing to use the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the proposed outlier fixed-loss cost threshold methodology.

Using this methodology, we used the formula described in section I.C.1 of this Addendum to simulate and calculate the Federal payment rate and outlier payments for all claims. In addition, as described in the earlier section to this Addendum, we are proposing to incorporate an estimate of FY 2021 outlier reconciliation in the methodology for determining the outlier threshold. As noted previously, for this FY 2021 proposed rule, the ratio of outlier reconciliation dollars to total Federal Payments (Step 4) is a negative 0.002787 percent, which, when rounded to the second digit, is 0.00 percent. Therefore, for FY 2021, we are proposing to incorporate a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.10 percent [5.1 percent-(-.00 percent)]. Under this proposed approach, we determined a threshold of $30,006 and calculated total outlier payments of $4,935,261,570 and total operating Federal payments of $91,833,641,321. We then divided total outlier payments by total operating Federal payments plus total outlier payments and determined that this threshold matched with the 5.10 percent target, which reflects our proposal to incorporate an estimate of outlier reconciliation in the determination of the outlier threshold (as discussed in more detail in the previous section of this Addendum). Since the target remains at 5.10 percent, we note that the threshold calculated without applying our proposed methodology for incorporating an estimate of outlier reconciliation in the determination of the outlier threshold is the same as identified previously at $30,006. We are proposing an outlier fixed-loss cost threshold for FY 2021 equal to the

prospective payment rate for the MS–DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, and any add-on payments for new technology, plus $30,006.

(2) Other Proposed Changes Concerning Outliers

As stated in the FY 1994 IPPS final rule (58 FR 46348), we establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. When we modeled the combined operating and capital outlier payments, we found that using a common threshold resulted in a higher percentage of outlier payments for capital-related costs than for operating costs. We project that the threshold for FY 2021 (which reflects our methodology to incorporate an estimate of operating outlier reconciliation) will result in outlier payments that will equal 5.1 percent of operating DRG payments and we estimate that capital outlier payments will equal 5.38 percent of capital payments based on the Federal rate (which reflects our methodology discussed previously to incorporate an estimate of capital outlier reconciliation).

In accordance with section 1886(d)(3)(B) of the Act and as discussed previously, we are proposing to reduce the FY 2021 standardized amount by the percentage of 5.1 percent to account for the projected proportion of payments paid as outliers.

The proposed outlier adjustment factors that would be applied to the operating standardized amount and capital Federal rate based on the proposed FY 2021 outlier threshold are as follows:

	Operating Standardized Amounts	Capital Federal Rate*
National	0.949	0.946097

*The adjustment factor for the capital federal rate includes an adjustment to the estimated percentage of FY 2021 capital outlier payments for capital outlier reconciliation, as discussed previously and in section X in the Addendum of this proposed rule.

We are proposing to apply the outlier adjustment factors to the proposed FY 2021 payment rates after removing the effects of the FY 2020 outlier adjustment factors on the standardized amount.

To determine whether a case qualifies for outlier payments, we currently apply hospital-specific CCRs to the total covered charges for the case. Estimated operating and capital costs for the case are calculated separately by applying separate operating and capital CCRs. These costs are then combined and compared with the outlier fixed-loss cost threshold.

Under our current policy at § 412.84, we calculate operating and capital CCR ceilings and assign a statewide average CCR for hospitals whose CCRs exceed 3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals. Based on this calculation, for hospitals for which the MAC computes operating CCRs greater than 1.156 or capital CCRs greater than 0.140, or hospitals for which the MAC is unable to calculate a CCR (as described under § 412.84(i)(3) of our regulations), statewide average CCRs are used to determine whether a hospital qualifies for outlier payments. Table 8A listed in section VI. of this Addendum (and available only via the internet on the CMS website) contains the proposed statewide average operating CCRs for urban hospitals and for rural hospitals for which the MAC is unable to compute a hospital-specific CCR within the range previously specified. These statewide average ratios would be effective for discharges occurring on or after October 1, 2020 and would replace the statewide average ratios from the prior fiscal year. Table 8B listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the comparable proposed statewide average capital CCRs. As previously stated, the proposed CCRs in Tables 8A and 8B would be used during FY 2021 when hospital-specific CCRs based on the latest settled cost report either are not available or are outside the range noted previously. Table 8C listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the proposed statewide average total CCRs used under the LTCH PPS as discussed in section V. of this Addendum.

We finally note that section 20.1.2 of chapter three of the Medicare Claims Processing Manual (on the internet at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*) covers an array of topics, including CCRs, reconciliation, and the time value of money. We encourage hospitals that are assigned the statewide average operating and/or capital CCRs to work with their MAC on a possible alternative operating and/or capital CCR as explained in the manual. Use of an alternative CCR developed by the hospital in conjunction with the MAC can avoid possible overpayments or underpayments at cost report settlement, thereby ensuring better accuracy when making outlier payments and negating the need for outlier reconciliation. We also note that a hospital may request an alternative operating or capital CCR at any time as long as the guidelines of the manual are followed. In addition, the manual outlines the outlier reconciliation process for hospitals and Medicare contractors. We refer hospitals to the manual instructions for complete details on outlier reconciliation.

(3) FY 2019 Outlier Payments

Our current estimate, using available FY 2019 claims data, is that actual outlier payments for FY 2019 were approximately 5.38 percent of actual total MS–DRG payments. Therefore, the data indicate that, for FY 2019, the percentage of actual outlier payments relative to actual total payments is higher than we projected for FY 2019. Consistent with the policy and statutory interpretation we have maintained since the inception of the IPPS, we do not make retroactive adjustments to outlier payments to ensure that total outlier payments for FY 2019 are equal to 5.1 percent of total MS–DRG payments. As explained in the FY 2003 Outlier Final Rule (68 FR 34502), if we were to make retroactive adjustments to all outlier payments to ensure total payments are 5.1 percent of MS–DRG payments (by retroactively adjusting outlier payments), we would be removing the important aspect of the prospective nature of the IPPS. Because such an across-the-board adjustment would either lead to more or less outlier payments for all hospitals, hospitals would no longer be able to reliably approximate their payment for a patient while the patient is still hospitalized. We believe it would be neither necessary nor appropriate to make such an aggregate retroactive adjustment. Furthermore, we believe it is consistent with the statutory language at section 1886(d)(5)(A)(iv) of the Act not to make retroactive adjustments to outlier payments. This section states that outlier payments be equal to or greater than 5 percent and less than or equal to 6 percent of projected or estimated (not actual) MS–DRG payments. We believe that an important goal of a PPS is predictability. Therefore, we believe that the fixed-loss outlier threshold should be projected based on the best available historical data and should not be adjusted retroactively. A retroactive change to the fixed-loss outlier threshold would affect all hospitals subject to the IPPS, thereby undercutting the predictability of the system as a whole.

We note that, because the MedPAR claims data for the entire FY 2020 will not be available until after September 30, 2020, we are unable to provide an estimate of actual outlier payments for FY 2020 based on FY 2019 claims data in this proposed rule. We will provide an estimate of actual FY 2020 outlier payments in the FY 2022 IPPS/LTCH PPS proposed rule.

5. Proposed FY 2021 Standardized Amount

The adjusted standardized amount is divided into labor-related and nonlabor-related portions. Tables 1A and 1B listed and published in section VI. of this Addendum (and available via the internet on the CMS website) contain the national standardized amounts that we are proposing to apply to all hospitals, except hospitals located in Puerto Rico, for FY 2021. The proposed standardized amount for hospitals in Puerto Rico is shown in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). The proposed amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the

standardized amounts in Table 1A is 68.3 percent, and the labor-related share applied to the standardized amounts in Table 1B is 62 percent. In accordance with sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act, we are proposing to apply a labor-related share of 62 percent, unless application of that percentage would result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we will apply a labor-related share of 62 percent for all hospitals whose wage indexes are less than or equal to 1.0000.

In addition, Tables 1A and 1B include the proposed standardized amounts reflecting the proposed applicable percentage increases for FY 2021.

The proposed labor-related and nonlabor-related portions of the national average standardized amounts for Puerto Rico hospitals for FY 2021 are set forth in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). Similarly, section 1886(d)(9)(C)(iv) of the Act, as amended by section 403(b) of Public Law 108–173, provides that the labor-related share for hospitals located in Puerto Rico be 62 percent, unless the application of that percentage would result in lower payments to the hospital.

The following table illustrates the changes from the FY 2020 national standardized amounts to the proposed FY 2021 national standardized amounts. The second through fifth columns display the changes from the FY 2019 standardized amounts for each applicable proposed FY 2021 standardized amount. The first row of the table shows the updated (through FY 2020) average standardized amount after restoring the FY 2020 offsets for outlier payments and the geographic reclassification budget neutrality. The MS–DRG reclassification and recalibration and wage index budget neutrality adjustment factors are cumulative. Therefore, those FY 2020 adjustment factors are not removed from this table. Additionally, for FY 2021 we have applied the proposed budget neutrality factor for the proposed policy for lowest quartile wage index hospitals and proposed transition, described previously.

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CHANGES FROM FY 2020 STANDARDIZED AMOUNTS TO THE PROPOSED FY 2021 STANDARDIZED AMOUNTS

	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
FY 2021 Base Rate after removing: 1. FY 2020 Geographic Reclassification Budget Neutrality (0.985447) 2. FY 2020 Operating Outlier Offset (0.949)	If Wage Index is Greater Than 1.0000: Labor (68.3%): $4,247.95 Nonlabor (31.7%): $1,971.59	If Wage Index is Greater Than 1.0000: Labor (68.3%): $4,247.95 Nonlabor (31.7%): $1,971.59	If Wage Index is Greater Than 1.0000: Labor (68.3%): $4,247.95 Nonlabor (31.7%): $1,971.59	If Wage Index is Greater Than 1.0000: Labor (68.3%): $4,247.95 Nonlabor (31.7%): $1,971.59
3. FY 2020 Rural Demonstration Budget Neutrality Factor (0.999771) 4. FY 2020 Lowest Quartile Budget Neutrality Factor (0.997894) 5. FY 2020 Transition Budget Neutrality Factor (0.998835)	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,856.11 Nonlabor (38%): $2,363.43	If Wage Index is less Than or Equal to 1.0000: Labor (62%) $3,856.11 Nonlabor (38%): $2,363.43	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,856.11 Nonlabor (38%): $2,363.43	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $3,856.11 Nonlabor (38%): $2,363.43
Proposed FY 2021 Update Factor	1.026	1.0035	1.0185	0.996
Proposed FY 2021 MS-DRG Recalibration Budget Neutrality Factor	0.998761	0.998761	0.998761	0.998761
Proposed FY 2021 Wage Index Budget Neutrality Factor	0.999362	0.999362	0.999362	0.999362
Proposed FY 2021 Reclassification Budget Neutrality Factor	0.988003	0.988003	0.988003	0.988003
Proposed FY 2021 Lowest Quartile Budget Neutrality Factor	0.998241	0.998241	0.998241	0.998241
Proposed FY 2021 Transition Budget Neutrality Factor	0.998580	0.998580	0.998580	0.998580
Proposed FY 2021 Operating Outlier Factor	0.949	0.949	0.949	0.949
Proposed FY 2021 Rural Demonstration Budget Neutrality Factor	0.999642	0.999642	0.999642	0.999642
Proposed FY 2021 Stem Cell Acquisition Budget Neutrality Factor	0.999861	0.999861	0.999861	0.999861
Adjustment for FY 2021 Required under Section 414 of Pub. L. 114-10 (MACRA)	1.005	1.005	1.005	1.005
Proposed National Standardized Amount for FY 2021 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (68.3/31.7)	**Labor: $4,084.16 Nonlabor: $1,895.58**	**Labor: $3,994.60 Nonlabor: $1,854.01**	**Labor: $4,054.31 Nonlabor: $1,881.72**	**Labor: $3,964.74 Nonlabor: $1,840.15**
Proposed National Standardized Amount for FY 2021 if Wage Index is Less Than or Equal to 1.0000; Labor/Non-Labor Share Percentage (62/38)	**Labor: $3,707.44 Nonlabor: $2,272.30**	**Labor: $3,626.14 Nonlabor: $2,222.47**	**Labor: $3,680.34 Nonlabor: $2,255.69**	**Labor: $3,599.03 Nonlabor: $2,205.86**

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B. Proposed Adjustments for Area Wage Levels and Cost-of-Living

Tables 1A through 1C, as published in section VI. of this Addendum (and available via the internet on the CMS website), contain the proposed labor-related and nonlabor-related shares that we are proposing to use to calculate the prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico for FY 2021. This section addresses two types of adjustments to the standardized amounts that are made in determining the proposed prospective payment rates as described in this Addendum.

1. Proposed Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-related portion of the national prospective payment rate to account for area differences in hospital wage levels. This adjustment is made by multiplying the labor-related portion of the adjusted standardized amounts by the appropriate wage index for the area in which the hospital is located. For FY 2021, as discussed in section IV.B.3. of the preamble of this proposed rule, we are proposing to apply a labor-related share of 68.3 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000. In section III. of the preamble of this proposed rule, we discuss the data and methodology for the proposed FY 2021 wage index.

2. Proposed Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act provides discretionary authority to the Secretary to make adjustments as the Secretary deems appropriate to take into account the unique circumstances of hospitals located in Alaska and Hawaii. Higher labor-related costs for these two States are taken into account in the adjustment for area wages described previously. To account for higher nonlabor-related costs for these two States, we multiply the nonlabor-related portion of the standardized amount for hospitals in Alaska and Hawaii by an adjustment factor.

In the FY 2013 IPPS/LTCH PPS final rule, we established a methodology to update the COLA factors for Alaska and Hawaii that were published by the U.S. Office of Personnel Management (OPM) every 4 years (at the same time as the update to the labor-related share of the IPPS market basket), beginning in FY 2014. We refer readers to the FY 2013 IPPS/LTCH PPS proposed and final rules for additional background and a detailed description of this methodology (77 FR 28145 through 28146 and 77 FR 53700 through 53701, respectively).

For FY 2018, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38530 through 38531), we updated 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.

Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, we are proposing to continue to use the same COLA factors in FY 2021 that were used in FY 2019 to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii. The following table lists the proposed COLA factors for FY 2021.

PROPOSED FY 2021 COST-OF-LIVING ADJUSTMENT FACTORS: ALASKA AND HAWAII HOSPITALS

Area	Cost of Living Adjustment Factor
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.25
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.25
City of Juneau and 80-kilometer (50-mile) radius by road	1.25
Rest of Alaska	1.25
City and County of Honolulu	1.25
County of Hawaii	1.21
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, the next update to the COLA factors for Alaska and Hawaii would occur at the same time as the update to the labor-related share of the IPPS market basket (no later than FY 2022).

C. Calculation of the Proposed Prospective Payment Rates

1. General Formula for Calculation of the Prospective Payment Rates for FY 2021

In general, the operating prospective payment rate for all hospitals (including hospitals in Puerto Rico) paid under the IPPS, except SCHs and MDHs, for FY 2021 equals the Federal rate (which includes uncompensated care payments).

Under current law, the MDH program has been extended for discharges occurring through September 30, 2022.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal national rate (which, as discussed in section V.G. of the preamble of this proposed rule, includes uncompensated care payments); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

The prospective payment rate for SCHs for FY 2021 equals the higher of the applicable Federal rate, or the hospital-specific rate as described later in this section. The prospective payment rate for MDHs for FY 2021 equals the higher of the Federal rate, or the Federal rate plus 75 percent of the difference between the Federal rate and the hospital-specific rate as described in this section. For MDHs, the updated hospital-specific rate is based on FY 1982, FY 1987, or FY 2002 costs per discharge, whichever yields the greatest aggregate payment.

2. Operating and Capital Federal Payment Rate and Outlier Payment Calculation

Note: The formula specified in this section is used for actual claim payment and is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital

CCRs for actual claim payment are from the PSF while CMS uses an adjusted CCR (as described previously) to project the threshold for the upcoming fiscal year. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier).

Step 1—Determine the MS–DRG and MS–DRG relative weight (from Table 5) for each claim based on the ICD–10–CM diagnosis and ICD–10–PCS procedure codes on the claim.

Step 2—Select the applicable average standardized amount depending on whether the hospital submitted qualifying quality data and is a meaningful EHR user, as described previously.

Step 3—Compute the operating and capital Federal payment rate:

—Federal Payment Rate for Operating Costs = MS–DRG Relative Weight × [(Labor-Related Applicable Standardized Amount × Applicable CBSA Wage Index) + (Nonlabor-Related Applicable Standardized Amount × Cost-of-Living Adjustment)] × (1 + IME + (DSH * 0.25))

—Federal Payment for Capital Costs = MS–DRG Relative Weight × Federal Capital Rate × Geographic Adjustment Fact × (l + IME + DSH)

Step 4—Determine operating and capital costs:

—Operating Costs = (Billed Charges × Operating CCR)

—Capital Costs = (Billed Charges × Capital CCR).

Step 5—Compute operating and capital outlier threshold (CMS applies a geographic adjustment to the operating and capital outlier threshold to account for local cost variation):

—Operating CCR to Total CCR = (Operating CCR)/(Operating CCR + Capital CCR)

—Operating Outlier Threshold = [Fixed Loss Threshold × ((Labor-Related Portion × CBSA Wage Index) + Nonlabor-Related portion)] × Operating CCR to Total CCR + Federal Payment with IME, DSH + Uncompensated Care Payment + New Technology Add-On Payment Amount

—Capital CCR to Total CCR = (Capital CCR)/(Operating CCR + Capital CCR)

—Capital Outlier Threshold = (Fixed Loss Threshold × Geographic Adjustment Factor × Capital CCR to Total CCR) + Federal Payment with IME and DSH

Step 6—Compute operating and capital outlier payments:

—Marginal Cost Factor = 0.80 or 0.90 (depending on the MS–DRG)

—Operating Outlier Payment = (Operating Costs—Operating Outlier Threshold) × Marginal Cost Factor

—Capital Outlier Payment = (Capital Costs—Capital Outlier Threshold) × Marginal Cost Factor

The payment rate may then be further adjusted for hospitals that qualify for a low-volume payment adjustment under section 1886(d)(12) of the Act and 42 CFR 412.101(b). The base-operating DRG payment amount may be further adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment as described under sections 1886(q) and 1886(o) of the Act, respectively. Payments also may be reduced by the 1-percent adjustment under the HAC Reduction Program as described in section 1886(p) of the Act. We also make new technology add-on payments in accordance with section 1886(d)(5)(K) and (L) of the Act. Finally, we add the uncompensated care payment to the total claim payment amount. As noted in the previous formula, we take uncompensated care payments and new technology add-on payments into consideration when calculating outlier payments.

3. Hospital-Specific Rate (Applicable Only to SCHs and MDHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: The Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

As noted previously, the MDH program has been extended under current law for discharges occurring through September 30, 2022. For MDHs, the updated hospital-specific rate is based on FY 1982, FY 1987, or FY 2002 costs per discharge, whichever yields the greatest aggregate payment.

For a more detailed discussion of the calculation of the hospital-specific rates, we refer readers to the FY 1984 IPPS interim final rule (48 FR 39772); the April 20, 1990 final rule with comment period (55 FR 15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS final rule (65 FR 47082).

b. Updating the FY 1982, FY 1987, FY 1996, FY 2002 and FY 2006 Hospital-Specific Rate for FY 2021

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs and MDHs equal to the update factor for all other IPPS hospitals, the update to the hospital-specific rates for SCHs and MDHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, the proposed applicable percentage increases to the hospital-specific rates applicable to SCHs and MDHs are the following:

FY 2021	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Proposed Market Basket Rate-of-Increase	3.0	3.0	3.0	3.0
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.75	-0.75
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-2.25	0	-2.25
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.4	-0.4	-0.4	-0.4
Proposed Applicable Percentage Increase Applied to Standardized Amount	**2.6**	**0.35**	**1.85**	**-0.4**

For a complete discussion of the applicable percentage increase applied to the hospital-specific rates for SCHs and MDHs, we refer readers to section IV.B. of the preamble of this proposed rule.

In addition, because SCHs and MDHs use the same MS–DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, the hospital-specific rate is adjusted by a budget neutrality factor to ensure that changes to the MS–DRG classifications and the recalibration of the MS–DRG relative weights are made in a manner so that aggregate IPPS payments are unaffected. Therefore, the hospital-specific rate for an SCH or an MDH is adjusted by the proposed MS–DRG reclassification and recalibration budget neutrality factor, as discussed in section III. of this Addendum and listed in the table in section II. of this Addendum. The resulting rate is used in determining the payment rate that an SCH or MDH would receive for its discharges beginning on or after October 1, 2020. We note that, in this proposed rule, for FY 2021, we are not proposing to make a documentation and coding adjustment to the hospital-specific rate. We refer readers to section II.D. of the preamble of this proposed rule for a complete discussion regarding our proposed policies and previously finalized policies (including our historical adjustments to the payment rates) relating to the effect of changes in documentation and coding that do not reflect real changes in case mix.

III. Proposed Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2021

The PPS for acute care hospital inpatient capital-related costs was implemented for cost reporting periods beginning on or after October 1, 1991. The basic methodology for determining Federal capital prospective rates is set forth in the regulations at 42 CFR 412.308 through 412.352. In this section of this Addendum, we discuss the factors that we are proposing to use to determine the capital Federal rate for FY 2021, which would be effective for discharges occurring on or after October 1, 2020.

All hospitals (except ''new'' hospitals under § 412.304(c)(2)) are paid based on the capital Federal rate. We annually update the capital standard Federal rate, as provided in § 412.308(c)(1), to account for capital input price increases and other factors. The regulations at § 412.308(c)(2) also provide that the capital Federal rate be adjusted annually by a factor equal to the estimated proportion of outlier payments under the capital Federal rate to total capital payments under the capital Federal rate. In addition, § 412.308(c)(3) requires that the capital Federal rate be reduced by an adjustment factor equal to the estimated proportion of payments for exceptions under § 412.348. (We note that, as discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53705), there is generally no longer a need for an exceptions payment adjustment factor.) However, in limited circumstances, an additional payment exception for extraordinary circumstances is provided for under § 412.348(f) for qualifying hospitals. Therefore, in accordance with § 412.308(c)(3), an exceptions payment adjustment factor may need to be applied if such payments are made. Section 412.308(c)(4)(ii) requires that the capital standard Federal rate be adjusted so that the effects of the annual DRG reclassification and the recalibration of DRG weights and changes in the geographic adjustment factor (GAF) are budget neutral.

Section 412.374 provides for payments to hospitals located in Puerto Rico under the IPPS for acute care hospital inpatient capital-related costs, which currently specifies capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the Federal rate.

A. Determination of the Proposed Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update for FY 2021

In the discussion that follows, we explain the factors that we are proposing to use to determine the capital Federal rate for FY 2021. In particular, we explain why the proposed FY 2021 capital Federal rate would increase approximately 1.30 percent, compared to the FY 2020 capital Federal rate. As discussed in the impact analysis in Appendix A to this proposed rule, we estimate that capital payments per discharge would increase approximately 0.6 percent during that same period. Because capital payments constitute approximately 10 percent of hospital payments, a 1-percent change in the capital Federal rate yields only approximately a 0.1 percent change in actual payments to hospitals.

1. Projected Capital Standard Federal Rate Update

Under § 412.308(c)(1), the capital standard Federal rate is updated on the basis of an analytical framework that takes into account changes in a capital input price index (CIPI) and several other policy adjustment factors. Specifically, we adjust the projected CIPI rate of change, as appropriate, each year for case-mix index-related changes, for intensity, and for errors in previous CIPI forecasts. The proposed update factor for FY 2021 under that framework is 1.5 percent based on a projected 1.5 percent increase in the 2014-based CIPI, a proposed 0.0 percentage point adjustment for intensity, a proposed 0.0 percentage point adjustment for case-mix, a proposed 0.0 percentage point adjustment for the DRG reclassification and recalibration, and a proposed forecast error correction of 0.0 percentage point. As discussed in section III.C. of this Addendum, we continue to believe that the CIPI is the most appropriate input price index for capital costs to measure capital price changes in a given year. We also explain the basis for the FY 2021 CIPI projection in that same section of this Addendum. In this section of this Addendum, we describe the proposed policy adjustments that we are proposing to apply in the update framework for FY 2021.

The case-mix index is the measure of the average DRG weight for cases paid under the IPPS. Because the DRG weight determines the prospective payment for each case, any percentage increase in the case-mix index corresponds to an equal percentage increase in hospital payments.

The case-mix index can change for any of several reasons—

- The average resource use of Medicare patient changes (''real'' case-mix change);
- Changes in hospital documentation and coding of patient records result in higher-weighted DRG assignments (''coding effects''); or
- The annual DRG reclassification and recalibration changes may not be budget neutral (''reclassification effect'').

We define real case-mix change as actual changes in the mix (and resource requirements) of Medicare patients, as opposed to changes in documentation and coding behavior that result in assignment of cases to higher-weighted DRGs, but do not reflect higher resource requirements. The capital update framework includes the same case-mix index adjustment used in the former operating IPPS update framework (as discussed in the May 18, 2004 IPPS proposed rule for FY 2005 (69 FR 28816)). (We no longer use an update framework to make a recommendation for updating the operating IPPS standardized amounts, as discussed in section II. of Appendix B to the FY 2006 IPPS final rule (70 FR 47707).)

For FY 2021, we are projecting a 0.5 percent total increase in the case-mix index. We estimated that the real case-mix increase would equal 0.5 percent for FY 2021. The net adjustment for change in case-mix is the difference between the projected real increase in case mix and the projected total increase in case mix. Therefore, the proposed net adjustment for case-mix change in FY 2021 is 0.0 percentage point.

The capital update framework also contains an adjustment for the effects of DRG reclassification and recalibration. This adjustment is intended to remove the effect on total payments of prior year's changes to the DRG classifications and relative weights, in order to retain budget neutrality for all case-mix index-related changes other than those due to patient severity of illness. Due to the lag time in the availability of data, there is a 2-year lag in data used to determine the adjustment for the effects of DRG reclassification and recalibration. For example, we have data available to evaluate the effects of the FY 2019 DRG reclassification and recalibration as part of our update for FY 2021. We assume, for purposes of this adjustment, that the estimate of FY 2019 DRG reclassification and recalibration would result in no change in the case-mix when compared with the case-mix index that would have resulted if we had not made the reclassification and recalibration changes to the DRGs. Therefore, we are proposing to make a 0.0 percentage point adjustment for reclassification and recalibration in the update framework for FY 2021.

The capital update framework also contains an adjustment for forecast error. The input price index forecast is based on historical trends and relationships ascertainable at the time the update factor is established for the upcoming year. In any given year, there may be unanticipated price fluctuations that may result in differences between the actual increase in prices and the forecast used in calculating the update factors. In setting a prospective payment rate under the framework, we make an adjustment for forecast error only if our estimate of the change in the capital input

price index for any year is off by 0.25 percentage point or more. There is a 2-year lag between the forecast and the availability of data to develop a measurement of the forecast error. Historically, when a forecast error of the CIPI is greater than 0.25 percentage point in absolute terms, it is reflected in the update recommended under this framework. A forecast error of 0.0 percentage point was calculated for the FY 2019 update, for which there are historical data. That is, current historical data indicated that the forecasted FY 2019 CIPI (1.4 percent) used in calculating the FY 2019 update factor was the same percentage increase as the actual realized price increase (1.4 percent). As this does not exceed the 0.25 percentage point threshold, we are not proposing an adjustment for forecast error in the update for FY 2021.

Under the capital IPPS update framework, we also make an adjustment for changes in intensity. Historically, we calculate this adjustment using the same methodology and data that were used in the past under the framework for operating IPPS. The intensity factor for the operating update framework reflects how hospital services are utilized to produce the final product, that is, the discharge. This component accounts for changes in the use of quality-enhancing services, for changes within DRG severity, and for expected modification of practice patterns to remove noncost-effective services. Our intensity measure is based on a 5-year average.

We calculate case-mix constant intensity as the change in total cost per discharge, adjusted for price level changes (the CPI for hospital and related services) and changes in real case-mix. Without reliable estimates of the proportions of the overall annual intensity changes that are due, respectively, to ineffective practice patterns and the combination of quality-enhancing new technologies and complexity within the DRG system, we assume that one-half of the annual change is due to each of these factors. Thus, the capital update framework provides an add-on to the input price index rate of increase of one-half of the estimated annual increase in intensity, to allow for increases within DRG severity and the adoption of quality-enhancing technology.

In this proposed rule, we are proposing to continue to use a Medicare-specific intensity measure that is based on a 5-year adjusted average of cost per discharge for FY 2021 (we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 0436) for a full description of our Medicare-specific intensity measure). Specifically, for FY 2021, we are proposing to use an intensity measure that is based on an average of cost-per-discharge data from the 5-year period beginning with FY 2014 and extending through FY 2018. Based on these data, we estimated that case-mix constant intensity declined during FYs 2014 through 2018. In the past, when we found intensity to be declining, we believed a zero (rather than a negative) intensity adjustment was appropriate. Consistent with this approach, because we estimated that intensity would decline during that 5-year period, we believe it is appropriate to continue to apply a zero-intensity adjustment for FY 2021. Therefore, we are proposing to make a 0.0 percentage point adjustment for intensity in the update for FY 2021.

Earlier, we described the basis of the components we used to develop the proposed 1.5 percent capital update factor under the capital update framework for FY 2021, as shown in the following table.

PROPOSED FY 2021 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index*	1.5
Intensity:	0.0
Case-Mix Adjustment Factors:	
Real Across DRG Change	0.5
Projected Case-Mix Change	-0.5
Subtotal	1.5
Effect of FY 2019 Reclassification and Recalibration	0.0
Forecast Error Correction	0.0
Total Proposed Update	1.5

*The capital input price index represents the 2014-based CIPI.

2. Outlier Payment Adjustment Factor

Section 412.312(c) establishes a unified outlier payment methodology for inpatient operating and inpatient capital-related costs. A shared threshold is used to identify outlier cases for both inpatient operating and inpatient capital-related payments. Section 412.308(c)(2) provides that the standard Federal rate for inpatient capital-related costs be reduced by an adjustment factor equal to the estimated proportion of capital-related outlier payments to total inpatient capital-related PPS payments. The outlier threshold is set so that operating outlier payments are projected to be 5.1 percent of total operating IPPS DRG payments. For FY 2021, we are proposing to incorporate the estimated outlier reconciliation payment amounts into the outlier threshold model, as we did for FY 2020. (For more details on our proposal to incorporate outlier reconciliation payment amounts into the outlier threshold model, please see section II.A. of this Addendum to this proposed rule.)

For FY 2020, we estimated that outlier payments for capital-related PPS payments would equal 5.37 percent of inpatient capital-related payments based on the capital Federal rate in FY 2020. Based on the threshold discussed in section II.A. of this Addendum, we estimate that prior to taking into account projected capital outlier reconciliation payments, outlier payments for capital-related costs would equal 5.40 percent for inpatient capital-related payments based on the proposed capital Federal rate in FY 2021. However, using the methodology outlined in section II.A. of this Addendum, we estimate that taking into account projected capital outlier reconciliation payments would decrease FY 2021 aggregate estimated capital outlier payments by 0.01 percent. Therefore, accounting for estimated capital outlier reconciliation, the estimated outlier payments for capital-related PPS payments would equal 5.39 percent (5.40 percent − 0.01 percent) of inpatient capital-related payments based on the capital Federal rate in FY 2021. Accordingly, we are proposing to apply an outlier adjustment factor of 0.9461 in determining the capital Federal rate for FY 2021. Thus, we estimate that the percentage of capital outlier payments to total capital Federal rate payments for FY 2021 would be higher than the percentage for FY 2020.

The outlier reduction factors are not built permanently into the capital rates; that is, they are not applied cumulatively in determining the capital Federal rate. The proposed FY 2021 outlier adjustment of 0.9461 is a −0.02 percent change from the FY 2020 outlier adjustment of 0.9463. Therefore, the proposed net change in the outlier adjustment to the capital Federal rate for FY 2021 is 0.9998 (0.9461/0.9463;

calculation performed on unrounded numbers) so that the proposed outlier adjustment would decrease the FY 2021 capital Federal rate by approximately 0.02 percent compared to the FY 2020 outlier adjustment.

3. Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the GAF

Section 412.308(c)(4)(ii) requires that the capital Federal rate be adjusted so that aggregate payments for the fiscal year based on the capital Federal rate, after any changes resulting from the annual DRG reclassification and recalibration and changes in the GAF, are projected to equal aggregate payments that would have been made on the basis of the capital Federal rate without such changes.

As discussed in section III.G.3. of the preamble of this proposed rule, in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42325 through 42339), we finalized a policy to help reduce wage index disparities between high and low wage index hospitals by increasing the wage index values for certain hospitals with low wage index values. As also discussed in section III.G.3. of the preamble of this proposed rule, this policy will continue in FY 2021. In addition, in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336), we removed urban to rural reclassifications from the calculation of the rural floor to prevent inappropriate payment increases under the rural floor due to rural reclassifications, such that, beginning in FY 2020, the rural floor is calculated without including the wage data of hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act (as implemented in the regulations at § 412.103). Therefore, as mentioned in section III.G.1. of the preamble of this proposed rule, the rural floor for this FY 2021 proposed rule is calculated without the wage data of hospitals that have reclassified as rural under § 412.103. Lastly, for FY 2020, we placed a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in FY 2019 (84 FR 42336 through 42338). In light of the proposed OMB updates described in section III.A.2. of the preamble of this proposed rule, for FY 2021 we are proposing to again cap any decreases in the wage index at 5 percent so that a hospital's final wage index for FY 2021 will not be less than 95 percent of its final wage index for FY 2020.

As we discussed in the in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42638 through 42639), we augmented our historical methodology for computing the budget neutrality factor for changes in the GAFs in light of the effect of those wage index changes on the GAFs. Specifically, we established a 2-step methodology, under which we first calculate a factor to ensure budget neutrality for changes to the GAFs due to the update to the wage data, wage index reclassifications and redesignations, including our policy to remove the wage data of urban hospitals that have reclassified as rural under § 412.103 from the calculation of ''the wage index for rural areas in the State in which the county is located'' in applying the provisions of section 1886(d)(8)(C)(iii) of the Act, and the rural floor, including our policy to calculate the rural floor without including the wage data of urban hospitals that have reclassified as rural under § 412.103, consistent with our historical GAF budget neutrality factor methodology. In the second step, we calculate a factor to ensure budget neutrality for changes to the GAFs due to our policy to increase the wage index for hospitals with a wage index value below the 25th percentile wage index and our proposed policy to place a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in the prior fiscal year. In this section, we refer to these two policies as the lowest quartile hospital wage index adjustment and the proposed 5-percent cap on wage index decreases.

In light of the proposed changes to the wage index and other wage index policies for FY 2021 discussed previously, which directly affect the GAF, we are proposing to continue to compute a budget neutrality factor for changes in the GAFs in two steps. We discuss our proposed 2-step calculation of the GAF budget neutrality factors for FY 2021 as follows.

To determine the GAF budget neutrality factors for FY 2021, we first compared estimated aggregate capital Federal rate payments based on the FY 2020 MS–DRG classifications and relative weights and the FY 2020 GAFs to estimated aggregate capital Federal rate payments based on the FY 2020 MS–DRG classifications and relative weights and the proposed FY 2021 GAFs without incorporating the effects on the GAFs of the lowest quartile hospital wage index adjustment and the proposed 5-percent cap on wage index decreases. To achieve budget neutrality for these changes in the GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 1.0025 for FY 2021. Next, we compared estimated aggregate capital Federal rate payments based on the proposed FY 2021 GAFs with and without incorporating the effects on the GAFs of the lowest quartile hospital wage index adjustment and the proposed 5-percent cap on wage index decreases. For this calculation, estimated aggregate capital Federal rate payments were calculated using the proposed FY 2021 MS–DRG classifications and relative weights, and the proposed FY 2021 GAFs (both with and without incorporating the effects on the GAF of the lowest quartile hospital wage index adjustment and the proposed 5-percent cap on wage index decreases). (We note, for this calculation the proposed GAFs included the out-migration and Frontier state adjustments.) To achieve budget neutrality for the effects of the lowest quartile hospital wage index adjustment and the proposed 5-percent cap on wage index decreases on the FY 2021 GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 0.99626. Therefore, to achieve budget neutrality for the proposed changes in the GAFs, based on the proposed calculations described previously, we are proposing to apply an incremental budget neutrality adjustment factor of 0.9987 (1.0025×0.9963) for FY 2021 to the previous cumulative FY 2020 adjustment factor.

We also compared estimated aggregate capital Federal rate payments based on the FY 2020 MS–DRG classifications and relative weights and the proposed FY 2021 GAFs to estimated aggregate capital Federal rate payments based on the cumulative effects of the proposed FY 2021 MS–DRG classifications and relative weights and the proposed FY 2021 GAFs without the effects of the lowest quartile hospital wage index adjustment and the proposed 5-percent cap on wage index decreases. The proposed incremental adjustment factor for proposed DRG classifications and changes in relative weights is 0.9995. The proposed incremental adjustment factors for proposed MS–DRG classifications and changes in relative weights (0.9995) and for proposed changes in the GAFs through FY 2021 (0.9987) is 0.9983 (0.9995×0.9987). We note that all the values are calculated with unrounded numbers.

The GAF/DRG budget neutrality adjustment factors are built permanently into the capital rates; that is, they are applied cumulatively in determining the capital Federal rate. This follows the requirement under § 412.308(c)(4)(ii) that estimated aggregate payments each year be no more or less than they would have been in the absence of the annual DRG reclassification and recalibration and changes in the GAFs.

The methodology used to determine the recalibration and geographic adjustment factor (GAF/DRG) budget neutrality adjustment is similar to the methodology used in establishing budget neutrality adjustments under the IPPS for operating costs. One difference is that, under the operating IPPS, the budget neutrality adjustments for the effect of geographic reclassifications are determined separately from the effects of other changes in the hospital wage index and the MS–DRG relative weights. Under the capital IPPS, there is a single GAF/DRG budget neutrality adjustment factor for changes in the GAF (including geographic reclassification and the lowest quartile hospital wage index adjustment and the proposed 5-percent cap on wage index decreases described previously) and the MS–DRG relative weights. In addition, there is no adjustment for the effects that geographic reclassification or the lowest quartile hospital wage index adjustment and the proposed 5-percent cap on wage index decreases described previously have on the other payment parameters, such as the payments for DSH or IME.

The proposed incremental GAF/DRG adjustment factor of 0.9983 (the product of the proposed incremental GAF budget neutrality adjustment factor of 0.9987 and the proposed incremental DRG budget neutrality adjustment factor of 0.9995) accounts for the proposed MS–DRG reclassifications and recalibration and for proposed changes in the GAFs. As noted previously, it also incorporates the effects on the GAFs of FY 2021 geographic reclassification decisions made by the MGCRB compared to FY 2020 decisions and the lowest quartile hospital wage index adjustment, and the proposed 5-percent cap on wage index decreases described earlier. However, it does not account for changes in payments due to changes in the DSH and IME adjustment factors.

4. Proposed Capital Federal Rate for FY 2021

For FY 2020, we established a capital Federal rate of $462.33 (84 FR 42640, as corrected in 84 FR 53613). We are proposing to establish an update of 1.5 percent in determining the FY 2021 capital Federal rate for all hospitals. As a result of this proposed update and the proposed budget neutrality factors discussed earlier, we are proposing to establish a national capital Federal rate of $468.36 for FY 2021. The proposed national capital Federal rate for FY 2021 was calculated as follows:

- The proposed FY 2021 update factor is 1.015; that is, the proposed update is 1.5 percent.
- The proposed FY 2021 budget neutrality adjustment factor that is applied to the capital Federal rate for proposed changes in the MS–DRG classifications and relative weights and proposed changes in the GAFs is 0.9983.
- The proposed FY 2021 outlier adjustment factor is 0.9461.

We are providing the following chart that shows how each of the proposed factors and adjustments for FY 2021 affects the computation of the proposed FY 2021 national capital Federal rate in comparison to the FY 2020 national capital Federal rate. The proposed FY 2021 update factor has the effect of increasing the capital Federal rate by 1.5 percent compared to the FY 2020 capital Federal rate. The proposed GAF/DRG budget neutrality adjustment factor has the effect of decreasing the capital Federal rate by 0.17 percent. The proposed FY 2021 outlier adjustment factor has the effect of decreasing the capital Federal rate by 0.02 percent compared to the FY 2020 capital Federal rate. The combined effect of all the proposed changes would increase the national capital Federal rate by approximately 1.30 percent, compared to the FY 2020 national capital Federal rate.

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2020 CAPITAL FEDERAL RATE AND THE PROPOSED FY 2021 CAPITAL FEDERAL RATE

	FY 2020	Proposed FY 2021	Proposed Change	Proposed Percent Change
Update Factor[1]	1.0150	1.0150	1.0150	1.50
GAF/DRG Adjustment Factor[1]	0.9948	0.9983	0.9983	-0.17
Outlier Adjustment Factor[2]	0.9463	0.9461	0.9998	-0.02
Capital Federal Rate	$462.33	$468.36	1.0130	1.30[3]

[1] The proposed update factor and the GAF/DRG budget neutrality adjustment factors are built permanently into the capital Federal rates. Thus, for example, the incremental change from FY 2020 to FY 2021 resulting from the application of the proposed 0.9983 GAF/DRG budget neutrality adjustment factor for FY 2021 is a net change of 0.9983 (or –0.17 percent).

[2] The outlier reduction factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the proposed FY 2021 outlier adjustment factor is 0.9461/0.9463 or 0.9998 (or -0.02 percent).

[3] Percent change may not sum due to rounding.

B. Calculation of the Proposed Inpatient Capital-Related Prospective Payments for FY 2021

For purposes of calculating payments for each discharge during FY 2021, the capital Federal rate is adjusted as follows: (Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME Adjustment Factor, if applicable). The result is the adjusted capital Federal rate.

Hospitals also may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. Section 412.312(c) provides for a shared threshold to identify outlier cases for both inpatient operating and inpatient capital-related payments. The proposed outlier threshold for FY 2021 is in section II.A. of this Addendum. For FY 2021, a case will qualify as a cost outlier if the cost for the case plus the (operating) IME and DSH payments (including both the empirically justified Medicare DSH payment and the estimated uncompensated care payment, as discussed in section II.A.4.j. of this Addendum) is greater than the prospective payment rate for the MS–DRG plus the proposed fixed-loss amount of $30,006.

Currently, as provided under § 412.304(c)(2), we pay a new hospital 85 percent of its reasonable costs during the first 2 years of operation, unless it elects to receive payment based on 100 percent of the capital Federal rate. Effective with the third year of operation, we pay the hospital based on 100 percent of the capital Federal rate (that is, the same methodology used to pay all other hospitals subject to the capital PPS).

C. Capital Input Price Index

1. Background

Like the operating input price index, the capital input price index (CIPI) is a fixed-weight price index that measures the price changes associated with capital costs during a given year. The CIPI differs from the operating input price index in one important aspect—the CIPI reflects the vintage nature of capital, which is the acquisition and use of capital over time. Capital expenses in any given year are determined by the stock of capital in that year (that is, capital that remains on hand from all current and prior capital acquisitions). An index measuring capital price changes needs to reflect this vintage nature of capital. Therefore, the CIPI was developed to capture the vintage nature of capital by using a weighted-average of past capital purchase prices up to and including the current year.

We periodically update the base year for the operating and capital input price indexes to reflect the changing composition of inputs for operating and capital expenses. For this FY 2021 IPPS/LTCH PPS proposed rule, we are proposing to use the rebased and revised IPPS operating and capital market baskets that reflect a 2014 base year. For a complete discussion of this rebasing, we refer readers to section IV. of the preamble of the FY 2018 IPPS/LTCH PPS final rule (82 FR 38170).

2. Forecast of the CIPI for FY 2021

Based on IHS Global Inc.'s fourth quarter 2019 forecast, for this proposed rule, we are forecasting the 2014-based CIPI to increase 1.5 percent in FY 2021. This reflects a projected 1.8 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 3.5 percent increase in other capital expense prices in FY 2021, partially offset by a projected 1.4 percent decline in vintage-weighted interest expense prices in FY 2021. The weighted average of these three factors produces the forecasted 1.5 percent increase for the 2014-based CIPI in FY 2021. We are also proposing that if more recent data becomes available after the publication of this proposed rule and before the publication of the final rule (for example, a more recent estimate of the increase in the 2014-based CIPI), we would use such data, if appropriate, to determine the FY 2021 increase in the 2014-based CIPI for the final rule.

IV. Proposed Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages for FY 2021

Payments for services furnished in children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) that are excluded from the IPPS are made on the basis of reasonable costs based on the hospital's own historical cost experience, subject to a rate-of-increase ceiling. A per discharge limit (the target amount, as defined in § 413.40(a) of the regulations) is set for each hospital, based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage specified in § 413.40(c)(3). In addition, as specified in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38536), effective for cost reporting periods beginning during FY 2018, the annual update to the target amount for extended neoplastic disease care hospitals (hospitals described in § 412.22(i) of the regulations) also is the rate-of-increase percentage specified in § 413.40(c)(3). (We note that, in accordance with § 403.752(a), religious nonmedical health care institutions (RNHCIs) are also subject to the rate-of increase limits established under § 413.40 of the regulations.)

For this FY 2021 IPPS/LTCH PPS proposed rule, based on IGI's fourth quarter 2019 forecast, we estimated that the 2014-based IPPS operating market basket update for FY 2021 would be 3.0 percent (that is, the estimate of the market basket rate-of-increase). Based on this estimate, the FY 2021 rate-of-increase percentage that would be applied to the FY 2020 target amounts in order to calculate the FY 2021 target amounts for children's hospitals, cancer hospitals, RNCHIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and extended neoplastic disease care hospitals would be 3.0 percent, in accordance with the applicable regulations at 42 CFR 413.40. However, we are proposing that if more recent data became available for the final rule, we would use them to calculate the IPPS operating market basket update for FY 2021.

IRFs and rehabilitation distinct part units, IPFs and psychiatric distinct part units, and LTCHs are excluded from the IPPS and paid under their respective PPSs. The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section VII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule for the updated changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2021. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

V. Proposed Changes to the Payment Rates for the LTCH PPS for FY 2021

A. Proposed LTCH PPS Standard Federal Payment Rate for FY 2021

1. Overview

In section VII. of the preamble of this proposed rule, we discuss our annual updates to the payment rates, factors, and specific policies under the LTCH PPS for FY 2021.

Under § 412.523(c)(3) of the regulations, for LTCH PPS FYs 2012 through 2020, we updated the standard Federal payment rate by the most recent estimate of the LTCH PPS market basket at that time, including additional statutory adjustments required by sections 1886(m)(3) (citing sections 1886(b)(3)(B)(xi)(II), and 1886(m)(4) of the Act as set forth in the regulations at § 412.523(c)(3)(viii) through (xv)). (For a summary of the payment rate development prior to FY 2012, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38310 through 38312) and references therein.)

Section 1886(m)(3)(A) of the Act specifies that, for rate year 2012 and each subsequent rate year, any annual update to the standard Federal payment rate shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (which we refer to as ''the multifactor productivity (MFP) adjustment'') as discussed in section VII.C.2 of the preamble of this proposed rule.

This section of the Act further provides that the application of section 1886(m)(3)(B) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. (As noted in section VII.C.2. of the preamble of this proposed rule, the annual update to the LTCH PPS occurs on October 1 and we have adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010. Therefore, for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use the term ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.) For LTCHs that fail to submit the required quality reporting data in accordance with the LTCH QRP, the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

2. Development of the Proposed FY 2021 LTCH PPS Standard Federal Payment Rate

Consistent with our historical practice, for FY 2021, we are proposing to apply the annual update to the LTCH PPS standard Federal payment rate from the previous year. Furthermore, in determining the proposed LTCH PPS standard Federal payment rate for FY 2021, we also are proposing to make certain regulatory adjustments, consistent with past practices. Specifically, in determining the proposed FY 2021 LTCH PPS standard Federal payment rate, we are proposing to apply a budget neutrality adjustment factor for the changes related to the area wage level adjustment (that is, changes to the wage data, labor-related share, and geographic labor-market area designations, and the proposed 5-percent cap on any decrease in a LTCH's wage index transition policy) as discussed in section V.B.6 of this Addendum to this proposed rule. In addition, we are proposing to apply the permanent budget neutrality adjustment factor (applied to LTCH PPS standard Federal payment rate cases only) for the cost of the elimination of the 25-percent threshold policy for FY 2021 (discussed in section VII.D. of the preamble of this proposed rule).

In this proposed rule, we are proposing to establish an annual update to the LTCH PPS standard Federal payment rate of 2.5 percent. Accordingly, as reflected in proposed § 412.523(c)(3)(xvii), we are proposing to apply a factor of 1.025 to the FY 2020 LTCH PPS standard Federal payment rate of $42,677.64 to determine the proposed FY 2021 LTCH PPS standard Federal payment rate. Also, as reflected in proposed § 412.523(c)(3)(xvii), applied in conjunction with the provisions of § 412.523(c)(4), we are proposing to establish an annual update to the LTCH PPS standard Federal payment rate of 0.5 percent (that is, an update factor of 1.005) for FY 2021 for LTCHs that fail to submit the required quality reporting data for FY 2021 as required under the LTCH QRP. Additionally, we are applying a permanent budget neutrality adjustment factor of 0.991249 to the LTCH PPS standard Federal payment rate for the cost of the elimination of the 25-percent threshold policy for FY 2021 and subsequent years after removing the temporary budget neutrality adjustment factor of 0.990737 that was applied to the LTCH PPS standard Federal payment rate for the cost of the elimination of the 25-percent threshold policy for FY 2020. Consistent with § 412.523(d)(4), we are proposing to apply an area wage level budget neutrality factor to the FY 2021 LTCH PPS standard Federal payment rate of 1.0018755, based on the best available data at this time, to ensure that any proposed changes to the general updates to the area wage level adjustment (that is, the annual update of the wage index, including any changes to the geographic labor-market area designations and labor-related share) would not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. Accordingly, we are proposing to establish an LTCH PPS standard Federal payment rate of $43,849.28 (calculated as $42,677.64 × 1.000517 × 1.025 × 1.0018755) for FY 2021 (calculations performed on rounded numbers). For LTCHs that fail to submit quality reporting data for FY 2021, in accordance with the requirements of the LTCH QRP under section 1866(m)(5) of the Act, we are proposing to establish an LTCH PPS standard Federal payment rate of $42,993.68 (calculated as $42,677.64 × 1.000517 × 1.005 × 1.0018755) (calculations performed on rounded numbers) for FY 2021.

B. Proposed Adjustment for Area Wage Levels Under the LTCH PPS for FY 2021

1. Background

Under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS standard Federal payment rate to account for differences in LTCH area wage levels under § 412.525(c). The labor-related

share of the LTCH PPS standard Federal payment rate is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The applicable LTCH PPS wage index is computed using wage data from inpatient acute care hospitals without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act.

The proposed FY 2021 LTCH PPS standard Federal payment rate wage index values that would be applicable for LTCH PPS standard Federal payment rate discharges occurring on or after October 1, 2020, through September 30, 2021, are presented in Table 12A (for urban areas) and Table 12B (for rural areas), which are listed in section VI. of the Addendum to this proposed rule and available via the internet on the CMS website.

2. Proposed Geographic Classifications (Labor Market Areas) for the LTCH PPS Standard Federal Payment Rate

In adjusting for the differences in area wage levels under the LTCH PPS, the labor-related portion of an LTCH's Federal prospective payment is adjusted by using an appropriate area wage index based on the geographic classification (labor market area) in which the LTCH is located. Specifically, the application of the LTCH PPS area wage level adjustment under existing § 412.525(c) is made based on the location of the LTCH—either in an ''urban area,'' or a ''rural area,'' as defined in § 412.503. Under § 412.503, an ''urban area'' is defined as a Metropolitan Statistical Area (MSA) (which includes a Metropolitan division, where applicable), as defined by the Executive OMB and a ''rural area'' is defined as any area outside of an urban area (75 FR 37246).

The CBSA-based geographic classifications (labor market area definitions) currently used under the LTCH PPS, effective for discharges occurring on or after October 1, 2014, are based on the OMB labor market area delineations based on the 2010 Decennial Census data. In general, the current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. (As noted elsewhere in this proposed rule, we have adopted minor revisions and updates in the years between the decennial censuses.) We adopted these labor market area delineations because they were at that time based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas. We also believed that these OMB delineations would ensure that the LTCH PPS area wage level adjustment most appropriately accounted for and reflected the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level. We noted that this policy was consistent with the IPPS policy adopted in FY 2015 under § 412.64(b)(1)(ii)(D) of the regulations (79 FR 49951 through 49963). (For additional information on the CBSA-based labor market area (geographic classification) delineations currently used under the LTCH PPS and the history of the labor market area definitions used under the LTCH PPS, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50180 through 50185).)

In general, it is our historical practice to update the CBSA-based labor market area delineations annually based on the most recent updates issued by 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. OMB Bulletin No. 17–01, issued August 15, 2017, established the delineations for the Nation's statistical areas, and the corresponding changes to the CBSA-based labor market areas were adopted in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41731). A copy of this bulletin may be obtained on the website at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf*. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42642), we adopted our current policy, that is, the continued use of the CBSA-based labor market area delineations as established in OMB Bulletin 17–01 and adopted in the FY 2019 IPPS/LTCH PPS final rule.

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. 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 based on the standards published on June 28, 2010 (75 FR 37246), and Census Bureau data. A copy of the September 14, 2018 OMB Bulletin No. 18–04, may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf*. (We note, 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*), and as discussed later in this section of this rule was not issued in time for development of this proposed rule.) While OMB Bulletin No. 18–04 is not based on new census data, it includes some material changes to the OMB statistical area delineations, including some new CBSAs, urban counties that would become rural, rural counties that would become urban, and existing CBSAs that would be split apart. In this proposed rule, under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we are proposing to adopt the revised delineations announced in OMB Bulletin No. 18–04 effective for FY 2021 under the LTCH PPS. As noted previously, the March 6, 2020 OMB Bulletin 20–01 was not issued in time for development of this proposed rule. The minor updates included in OMB Bulletin 20–01 do not alter the urban or rural status of any county, and would not impact our proposed updates to the CBSA-based labor market area delineations discussed in this section of the rule. This proposal to adopt the revised delineations announced in OMB Bulletin No. 18–04 is consistent with the changes proposed under the IPPS for FY 2021 as discussed in section III.A.2. of the preamble of this proposed rule. A summary of these proposed changes is presented in the discussion that follows in this section. For complete details on the proposed changes we refer readers to section III.A.2. of the preamble of this proposed rule.

a. Urban Counties That Would Become Rural Under the Revised OMB Delineations

Analysis of the revised OMB labor market area delineations shows that a total of 34 counties (and county equivalents) currently considered part of an urban CBSA would be considered to be located in a rural area beginning in FY 2021 under our proposal to adopt the revisions to the OMB delineations based on OMB Bulletin No. 18–04. The chart in section III.A.2.ii. of the preamble of this proposed rule lists the 34 urban counties that would be rural under these revisions to the OMB delineations.

b. Rural Counties That Would Become Urban Under the Revised OMB Delineations

Analysis of the revised labor market area delineations shows that a total of 47 counties (and county equivalents) located in rural areas that would be located in urban areas beginning in FY 2021 under our proposal to adopt the revisions to the OMB delineations based on OMB Bulletin No. 18–04. The chart in section III.A.2.iii. of the preamble of this proposed rule lists the 47 rural counties that would be urban under these revised OMB delineations.

c. Urban Counties That Would Move to a Different Urban CBSA Under the Revised OMB Delineations

In addition to rural counties becoming urban and urban counties becoming rural, some urban counties would shift from one urban CBSA to another urban CBSA under our proposal to adopt the revised delineations announced in OMB Bulletin No. 18–04. In other cases, adopting the revised delineations announced in OMB Bulletin No. 18–04 would involve a change only in CBSA name and/or number, while the CBSA continues to encompass the same constituent counties. For example, CBSA 19380 (Dayton, OH) would experience both a change to its number and its name, and become CBSA 19430 (Dayton-Kettering, OH), while all of its three constituent counties would remain the same. In other cases, only the name of the CBSA would be modified, and none of the currently assigned counties would be reassigned to a different urban CBSA. The chart in section III.A.2.iii. of the preamble of this proposed rule lists the CBSAs where we are proposing to change the name and/or CBSA number only.

There are also counties that would shift between existing and new CBSAs, changing the constituent makeup of the CBSAs, under our proposal to adopt the revisions to the OMB delineations based on OMB Bulletin No. 18–04. For example, some CBSAs would be split into multiple new CBSAs, or a CBSA would lose one or more counties to other urban CBSAs. The chart in section III.A.2.iv. of the preamble of this proposed rule lists the urban counties that would move from one urban CBSA to a new or modified CBSA

under our proposal to adopt these revisions to the OMB delineations. We believe these revisions to the CBSA-based labor market area delineations as established in OMB Bulletin 18–04 would ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas (81 FR 57298). Therefore, we are proposing to adopt the revisions announced in OMB Bulletin No. 18–04 to the CBSA-based labor market area delineations under the LTCH PPS, effective October 1, 2020. Accordingly, the proposed FY 2021 LTCH PPS wage index values in Tables 12A and 12B listed in section VI. of the Addendum to this proposed rule (which are available via the internet on the CMS website) reflect the proposed revisions to the CBSA-based labor market area delineations previously described. We note that, as discussed in section III.A.2. of the preamble of this proposed rule, these revisions to the CBSA-based delineations also are being proposed under the IPPS.

As indicated previously, overall, we believe that our proposal to adopt the revised delineations announced in OMB Bulletin No. 18–04 would result in LTCH PPS wage index values being more representative of the actual costs of labor in a given area. However, we also recognize that some LTCHs would experience decreases in their area wage index values as a result of our proposal. We also realize that many LTCHs would have higher area wage index values under our proposal. To mitigate the impact upon LTCHs, we have in the past provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts. While we believe that using the new OMB delineations would create a more accurate payment adjustment for differences in area wage levels, we also recognize that adopting such changes may cause some short-term instability in LTCH PPS payments. As discussed in section V.B.5. of the Addendum to this proposed rule, we are proposing a transition policy to help mitigate any significant negative impacts that LTCHs may experience due to our proposal to adopt the revised OMB delineations under the LTCH PPS. Consistent with past practice, we are proposing that this proposed transition would be implemented in a budget neutral manner, as discussed in section V.B.6. of the Addendum to this proposed rule.

3. Proposed Labor-Related Share for the LTCH PPS Standard Federal Payment Rate

Under the payment adjustment for the differences in area wage levels under § 412.525(c), the labor-related share of an LTCH's standard Federal payment rate payment is adjusted by the applicable wage index for the labor market area in which the LTCH is located. The LTCH PPS labor-related share currently represents the sum of the labor-related portion of operating costs and a labor-related portion of capital costs using the applicable LTCH market basket. Additional background information on the historical development of the labor-related share under the LTCH PPS can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817 and 27829 through 27830) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766 through 51769 and 51808).

For FY 2013, we rebased and revised the market basket used under the LTCH PPS by adopting a 2009-based LTCH market basket. In addition, beginning in FY 2013, we determined the labor-related share annually as the sum of the relative importance of each labor-related cost category of the 2009-based LTCH market basket for the respective fiscal year based on the best available data. (For more details, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53477 through 53479). Then, effective for FY 2017, we rebased and revised the 2009-based LTCH market basket to reflect a 2013 base year and determined the labor-related share annually as the sum of the relative importance of each labor-related cost category in the 2013-based LTCH market basket using the most recent available data. (For more details, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57085 through 57096).)

As noted previously in section V.A. in this Addendum to this proposed rule, effective for FY 2021, we are proposing to rebase and revise the 2013-based LTCH market basket to reflect a 2017 base year. In conjunction with that proposal, as discussed in section VII.D.6. of the preamble of this proposed rule, we are also proposing that the LTCH PPS labor-related share for FY 2021 would be the sum of the FY 2021 relative importance of each labor-related cost category in the proposed 2017-based LTCH market basket using the most recent available data. Table E9 in section VII.D.6. of the preamble of this proposed rule shows the proposed FY 2021 labor-related share using the proposed 2017-based LTCH market basket and the FY 2020 labor-related share using the 2013-based LTCH market basket. The proposed labor-related share for FY 2021 is the sum of the 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 cost weight from the proposed 2017-based LTCH market basket. The relative importance reflects the different rates of price change for these cost categories between the base year (2017) and FY 2021. Based on IHS Global Inc.'s 4th quarter 2019 forecast of the proposed 2017-based LTCH market basket, the sum of the FY 2021 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 63.6 percent. We propose that the portion of Capital-Related costs that is influenced by the local labor market is 46 percent, which is the same percentage applied to the 2013-based LTCH market basket. Since the FY 2021 relative importance for Capital-Related is 9.5 percent based on IHS Global Inc.'s 4th quarter 2019 forecast of the proposed 2017-based LTCH market basket, we took 46 percent of 9.5 percent to determine the proposed labor-related share of Capital-Related for FY 2021 of 4.4 percent. Therefore, we are proposing a total labor-related share for FY 2021 of 68.0 percent (the sum of 63.6 percent for the operating cost and 4.4 percent for the labor-related share of Capital-Related). The total difference between the proposed FY 2021 labor-related share using the proposed 2017-based LTCH market basket and the FY 2020 labor-related share using the 2013-based LTCH market basket is 1.7 percentage points (68.0 percent and 66.3 percent, respectively). As discussed in greater detail in section VII.D.6. of the preamble of this proposed rule, this difference is attributable to the revision to the base year cost weights, the revision to the starting point of the calculation of relative importance (base year) from 2013 to 2017, and the use of an updated IHS Global Inc. forecast and reflecting an additional year of inflation. Consistent with our historical practice, we also propose that if more recent data became available, we would use that data, if appropriate, to determine the final FY 2021 labor-related share in the final rule.

4. Proposed Wage Index for FY 2021 for the LTCH PPS Standard Federal Payment Rate

Historically, we have established LTCH PPS area wage index values calculated from acute care IPPS hospital wage data without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act (67 FR 56019). The area wage level adjustment established under the LTCH PPS is based on an LTCH's actual location without regard to the ''urban'' or ''rural'' designation of any related or affiliated provider.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42643), we calculated the FY 2020 LTCH PPS area wage index values using the same data used for the FY 2020 acute care hospital IPPS (that is, data from cost reporting periods beginning during FY 2016), without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act, as these were the most recent complete data available at that time. In that same final rule, we indicated that we computed the FY 2020 LTCH PPS area wage index values, consistent with the urban and rural geographic classifications (labor market areas) that were in place at that time and consistent with the pre-reclassified IPPS wage index policy (that is, our historical policy of not taking into account IPPS geographic reclassifications in determining payments under the LTCH PPS). As with the IPPS wage index, wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus (or campuses) are located. We also continued to use our existing policy for determining area wage index values for areas where there are no IPPS wage data.

Consistent with our historical methodology, to determine the applicable area wage index values for the FY 2021 LTCH PPS standard Federal payment rate, under the broad authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we are proposing to continue to

employ our historical practice of using the same data we are proposing to use to compute the proposed FY 2021 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this proposed rule, that is wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2017, because these data are the most recent complete data available.

In addition, we are proposing to compute the FY 2021 LTCH PPS standard Federal payment rate area wage index values consistent with the ''urban'' and ''rural'' geographic classifications (that is, the proposed labor market area delineations, including the updates, as previously discussed in section V.B. of this Addendum) and our historical policy of not taking into account IPPS geographic reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act in determining payments under the LTCH PPS. We are also proposing to continue to apportion the wage data for multicampus hospitals with campuses located in different labor market areas to each CBSA where the campus or campuses are located, consistent with the IPPS policy. Lastly, consistent with our existing methodology for determining the LTCH PPS wage index values, for FY 2021, we are proposing to continue to use our existing policy for determining area wage index values for areas where there are no IPPS wage data. Under our existing methodology, the LTCH PPS wage index value for urban CBSAs with no IPPS wage data would be determined by using an average of all of the urban areas within the State, and the LTCH PPS wage index value for rural areas with no IPPS wage data would be determined by using the unweighted average of the wage indices from all of the CBSAs that are contiguous to the rural counties of the State.

Based on the FY 2017 IPPS wage data that we are proposing to use to determine the proposed FY 2021 LTCH PPS standard Federal payment rate area wage index values in this final rule, there are no IPPS wage data for the urban area of Hinesville, GA (CBSA 25980). Consistent with our existing methodology, we calculated the proposed FY 2021 wage index value for CBSA 25980 as the average of the wage index values for all of the other urban areas within the State of Georgia (that is, CBSAs 10500, 12020, 12060, 12260, 15260, 16860, 17980, 19140, 23580, 31420, 40660, 42340, 46660 and 47580), as shown in Table 12A, which is listed in section VI. of the Addendum to this proposed rule and available via the internet on the CMS website.

Based on the FY 2017 IPPS wage data that we are proposing to use to determine the proposed FY 2021 LTCH PPS standard Federal payment rate area wage index values in this proposed rule, there are no rural areas without IPPS hospital wage data. Therefore, it is not necessary to use our established methodology to calculate a proposed LTCH PPS standard Federal payment rate wage index value for rural areas with no IPPS wage data for FY 2021. We note that, as IPPS wage data are dynamic, it is possible that the number of rural areas without IPPS wage data will vary in the future.

5. Proposed Transition Wage Index for LTCHs Negatively Impacted

As discussed in section V.B.2. of the Addendum to this proposed rule, overall, we believe that our proposal to adopt the revised OMB delineations announced in Bulletin No. 18–04 for FY 2021 would result in LTCH PPS wage index values being more representative of the actual costs of labor in a given area. However, we also recognize that some LTCHs would experience decreases in their area wage index values as a result of our proposal. We also realize that some LTCHs would have higher area wage index values under our proposal.

To mitigate the potential impacts of proposed policies on LTCHs, we have in the past provided for transition periods when adopting changes that have significant payment implications, particularly large negative impacts. For example, we have proposed and finalized budget neutral transition policies to help mitigate negative impacts on LTCHs following the adoption of the new CBSA delineations based on the 2010 decennial census data in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50185). Specifically, we implemented a 1-year 50/50 blended wage index for any LTCHs that experienced a decrease in wage index values due to our adoption of the revised delineations. This required calculating and comparing two wage indexes for each LTCH since that blended wage index was computed as the sum of 50 percent of the FY 2015 LTCH PPS wage index values under the FY 2014 CBSA delineations and 50 percent of the FY 2015 LTCH PPS wage index values under the FY 2015 new OMB delineations. While we believed that using the new OMB delineations would ultimately create a more accurate payment adjustment for differences in area wage levels, we also recognized that adopting such changes may cause some short-term instability in LTCH PPS payments. Similar instability may result from the proposed wage policies herein, in particular for LTCHs that would be negatively impacted by the proposed adoption of the updates to the OMB delineations. For example, LTCH's currently located in CBSA 35614 (New York-Jersey City-White Plains, NY-NJ) that would be located in new CBSA 35154 (New Brunswick-Lakewood, NJ) under the proposed changes to the CBSA-based labor market area delineations would experience a nearly 17 percent decrease in the wage index as a result of the proposed change.

Consistent with our past practice of implementing transition policies to help mitigate negative impacts on hospitals following the adoption of the new CBSA delineations, we believe that if we adopt the revised delineations announced in OMB Bulletin 18–04, it would be appropriate to implement a transition policy since, as mentioned previously, some of these revisions are material, and may negatively impact payments to LTCHs. Similar to the policy proposed under the IPPS for the proposed adoption of the revised delineations announced in OMB Bulletin 18–04 discussed in section III.A.2. of the preamble to this proposed rule, we believe applying a 5-percent cap on any decrease in an LTCH's wage index from the LTCH's final wage index from the prior fiscal year would be an appropriate transition for FY 2021 for the revised OMB delineations as it provides transparency and predictability in payment levels from FY 2020 to the upcoming FY 2021. The proposed FY 2021 5-percent cap on wage index decreases would be applied to all LTCHs that have any decrease in their wage indexes, regardless of the circumstance causing the decline. Given the significant portion of Medicare LTCH PPS payments that are adjusted by the wage index and how relatively few LTCHs generally see wage index declines in excess of 5 percent, LTCHs may have difficulty adapting to changes in the wage index of this magnitude all at once. For these reasons, under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we are proposing to apply a 5-percent cap on any decrease in a LTCH's wage index from the LTCH's wage index from the prior fiscal year such that that an LTCH's final wage index for FY 2021 would not be less than 95 percent of its final wage index for FY 2020. This transition would allow the effects of our proposed adoption of the revised CBSA delineations to be phased in over 2 years, where the estimated reduction in an LTCH's wage index would be capped at 5 percent in FY 2021 (that is, no cap would be applied to the reduction in the wage index for the second year (FY 2022)). Because we believe that using the new OMB delineations would ultimately create a more accurate payment adjustment for differences in area wage levels we are not proposing to include a cap on the overall increase in an LTCH's wage index value.

Furthermore, consistent with the requirement at § 412.525(c)(2) that changes to area wage level adjustments are made in a budget neutral manner, we are proposing that this proposed 5 percent cap on the decrease on an LTCH's wage index would not result in any change in estimated aggregate LTCH PPS payments by including the application of this policy in the determination of the proposed area wage level budget neutrality factor that is applied to the standard Federal payment rate, which is discussed in section V.B.6. of the Addendum to this proposed rule.

6. Proposed Budget Neutrality Adjustments for Changes to the LTCH PPS Standard Federal Payment Rate Area Wage Level Adjustment

Historically, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. Under § 412.525(c)(2), any changes to the area wage index values or labor-related share are to be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected; that is, will be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this policy, we determine an area wage level adjustment budget neutrality factor that is applied to the standard Federal payment rate to ensure that any changes to the area wage level adjustments are budget neutral such that any changes to the area wage index values or labor-related share would not result

in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Accordingly, under § 412.523(d)(4), we have applied an area wage level adjustment budget neutrality factor in determining the standard Federal payment rate, and we also established a methodology for calculating an area wage level adjustment budget neutrality factor. (For additional information on the establishment of our budget neutrality policy for changes to the area wage level adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771 through 51773 and 51809).)

For FY 2021, in accordance with § 412.523(d)(4), we are proposing to apply an area wage level budget neutrality factor to adjust the LTCH PPS standard Federal payment rate to account for the estimated effect of the adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments, consistent with the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773). As discussed previously, we are proposing that the proposed 5 percent cap on the decrease on an LTCH's wage index would be implemented in a budget neutral manner by including the application of that proposed policy in the area wage level a budget neutrality factor that is applied to the standard Federal payment rate.

Specifically, we are proposing to determine an area wage level adjustment budget neutrality factor that would be applied to the LTCH PPS standard Federal payment rate under § 412.523(d)(4) for FY 2021 using the following methodology:

Step 1—Simulate estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2020 wage index values, the FY 2020 labor-related share of 66.3 percent, and the FY 2020 labor market area designations.

Step 2—Simulate estimated aggregate LTCH PPS standard Federal payment rate payments using the proposed FY 2021 wage index values based on updated hospital wage data, including the proposed 5 percent cap on the decrease on an LTCH's wage index, the proposed FY 2021 labor-related share of 68.0 percent, and the proposed FY 2021 labor market area designations. (As noted previously, the proposed changes to the wage index values based on updated hospital wage data are discussed in section V.B.4.a. of this Addendum to this proposed rule; the proposed transitional 5 percent cap on the decrease on an LTCH's wage index is discussed in section V.B.5. of this Addendum to this proposed rule, the proposed labor-related share is discussed in section V.B.3. of this Addendum to this proposed rule, and proposed changes to the geographic labor-market area designations are discussed in section V.B.2. of this Addendum to this proposed rule.)

Step 3—Calculate the ratio of these estimated total LTCH PPS standard Federal payment rate payments by dividing the estimated total LTCH PPS standard Federal payment rate payments using the FY 2020 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS standard Federal payment rate payments using the proposed FY 2021 general updates to the area wage level adjustment (calculated in Step 2) to determine the proposed budget neutrality factor for general updates to the area wage level adjustment for FY 2021 LTCH PPS standard Federal payment rate payments.

Step 4—Apply the proposed FY 2021 general updates to the area wage level adjustment budget neutrality factor from Step 3 to determine the proposed FY 2021 LTCH PPS standard Federal payment rate after the application of the proposed FY 2021 annual update.

We note that, because the area wage level adjustment under § 412.525(c) is an adjustment to the LTCH PPS standard Federal payment rate, consistent with historical practice, we only used data from claims that qualified for payment at the LTCH PPS standard Federal payment rate under the dual rate LTCH PPS to calculate the proposed FY 2021 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor. In addition, we note that the estimated LTCH PPS standard Federal payment rate used in the calculations in Steps 1 through 4 include the permanent one-time budget neutrality adjustment factor for the estimated cost of eliminating the 25-percent threshold policy in FY 2021 and subsequent years (discussed in section VII.D. of the preamble of this proposed rule).

For this proposed rule, using the steps in the methodology previously described, we determined a proposed FY 2021 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor of 1.0018755. Accordingly, in section V.A. of the Addendum to this proposed rule, to determine the proposed FY 2021 LTCH PPS standard Federal payment rate, we applied the proposed area wage level adjustment budget neutrality factor of 1.0018755, in accordance with § 412.523(d)(4).

C. Proposed LTCH PPS Cost-of-Living Adjustment (COLA) for LTCHs Located in Alaska and Hawaii

Under § 412.525(b), a cost-of-living adjustment (COLA) is provided for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States. Specifically, we apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal payment rate by the applicable COLA factors established annually by CMS. Higher labor-related costs for LTCHs located in Alaska and Hawaii are taken into account in the adjustment for area wage levels previously described. The methodology used to determine the COLA factors for Alaska and Hawaii is based on a comparison of the growth in the Consumer Price Indexes (CPIs) for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). It also includes a 25-percent cap on the CPI-updated COLA factors. Under our current policy, we update the COLA factors using the methodology as previously described every 4 years (at the same time as the update to the labor-related share of the IPPS market basket), and we last updated the COLA factors for Alaska and Hawaii published by OPM for 2009 in FY 2018 (82 FR 38539 through 38540).

We continue to believe that determining updated COLA factors using this methodology would appropriately adjust the nonlabor-related portion of the LTCH PPS standard Federal payment rate for LTCHs located in Alaska and Hawaii. Therefore, in this proposed rule, for FY 2021, under the broad authority conferred upon the Secretary by section 123 of the BBRA, as amended by section 307(b) of the BIPA, to determine appropriate payment adjustments under the LTCH PPS, we are proposing to continue to use the COLA factors based on the 2009 OPM COLA factors updated through 2016 by the comparison of the growth in the CPIs for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as established in the FY 2018 IPPS/LTCH PPS final rule. (For additional details on our current methodology for updating the COLA factors for Alaska and Hawaii and for a discussion on the FY 2018 COLA factors, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38539 through 38540).)

PROPOSED COST-OF-LIVING ADJUSTMENT FACTORS FOR ALASKA AND HAWAII UNDER THE LTCH PPS FOR FY 2021

Area	FY 2021
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.25
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.25
City of Juneau and 80-kilometer (50-mile) radius by road	1.25
Rest of Alaska	1.25
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.21
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

D. Proposed Adjustment for LTCH PPS High Cost Outlier (HCO) Cases

1. HCO Background

From the beginning of the LTCH PPS, we have included an adjustment to account for cases in which there are extraordinarily high costs relative to the costs of most discharges. Under this policy, additional payments are made based on the degree to which the estimated cost of a case (which is calculated by multiplying the Medicare allowable covered charge by the hospital's overall hospital CCR) exceeds a fixed-loss amount. This policy results in greater payment accuracy under the LTCH PPS and the Medicare program, and the LTCH sharing the financial risk for the treatment of extraordinarily high-cost cases.

We retained the basic tenets of our HCO policy in FY 2016 when we implemented the dual rate LTCH PPS payment structure under section 1206 of Public Law 113–67. LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid at the LTCH PPS standard Federal payment rate, which includes, as applicable, HCO payments under § 412.523(e). LTCH discharges that do not meet the criteria for exclusion are paid at the site neutral payment rate, which includes, as applicable, HCO payments under § 412.522(c)(2)(i). In the FY 2016 IPPS/LTCH PPS final rule, we established separate fixed-loss amounts and targets for the two different LTCH PPS payment rates. Under this bifurcated policy, the historic 8-percent HCO target was retained for LTCH PPS standard Federal payment rate cases, with the fixed-loss amount calculated using only data from LTCH cases that would have been paid at the LTCH PPS standard Federal payment rate if that rate had been in effect at the time of those discharges. For site neutral payment rate cases, we adopted the operating IPPS HCO target (currently 5.1 percent) and set the fixed-loss amount for site neutral payment rate cases at the value of the IPPS fixed-loss amount. Under the HCO policy for both payment rates, an LTCH receives 80 percent of the difference between the estimated cost of the case and the applicable HCO threshold, which is the sum of the LTCH PPS payment for the case and the applicable fixed-loss amount for such case.

In order to maintain budget neutrality, consistent with the budget neutrality requirement at § 412.522(d)(1) for HCO payments to LTCH PPS standard Federal rate payment cases, we also adopted a budget neutrality requirement for HCO payments to site neutral payment rate cases by applying a budget neutrality factor to the LTCH PPS payment for those site neutral payment rate cases. (We refer readers to § 412.522(c)(2)(i) of the regulations for further details.) We note that, during the 4-year transitional period, the site neutral payment rate HCO budget neutrality factor did not apply to the LTCH PPS standard Federal payment rate portion of the blended payment rate at § 412.522(c)(3) payable to site neutral payment rate cases. (For additional details on the HCO policy adopted for site neutral payment rate cases under the dual rate LTCH PPS payment structure, including the budget neutrality adjustment for HCO payments to site neutral payment rate cases, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49617 through 49623).)

2. Determining LTCH CCRs Under the LTCH PPS

a. Background

As noted previously, CCRs are used to determine payments for HCO adjustments for both payment rates under the LTCH PPS and also are used to determine payments for site neutral payment rate cases. As noted earlier, in determining HCO and the site neutral payment rate payments (regardless of whether the case is also an HCO), we generally calculate the estimated cost of the case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. An overall CCR is used because the LTCH PPS uses a single prospective payment per discharge that covers both inpatient operating and capital-related costs. The LTCH's overall CCR is generally computed based on the sum of LTCH operating and capital costs (as described in Section 150.24, Chapter 3, of the Medicare Claims Processing Manual (Pub. 100–4)) as compared to total Medicare charges (that is, the sum of its operating and capital inpatient routine and ancillary charges), with those values determined from either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period. However, in certain instances, we use an alternative CCR, such as the statewide average CCR, a CCR that is specified by CMS, or one that is requested by the hospital. (We refer readers to § 412.525(a)(4)(iv) of the regulations for further details regarding HCO adjustments for either LTCH PPS payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate.)

The LTCH's calculated CCR is then compared to the LTCH total CCR ceiling. Under our established policy, an LTCH with a calculated CCR in excess of the applicable maximum CCR threshold (that is, the LTCH total CCR ceiling, which is calculated as 3 standard deviations from the national geometric average CCR) is generally assigned the applicable statewide CCR. This policy is premised on a belief that calculated CCRs above the LTCH total CCR ceiling are most likely due to faulty data reporting or entry, and CCRs based on erroneous data should not be used to identify and make payments for outlier cases.

b. Proposed LTCH Total CCR Ceiling

Consistent with our historical practice, we are proposing to use the most recent data available to determine the LTCH total CCR ceiling for FY 2021 in this proposed rule. Specifically, in this proposed rule, we are proposing to use our established methodology for determining the LTCH total CCR ceiling based on IPPS total CCR data from the December 2019 update of the Provider Specific File (PSF), which is the most recent data available, we are proposing to establish an LTCH total CCR ceiling of 1.251 under the LTCH PPS for FY 2021 in accordance with § 412.525(a)(4)(iv)(C)(*2*) for HCO cases under either payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate. Consistent with our historical practice, we are proposing to use more recent data to determine the LTCH total CCR ceiling for FY 2021 proposed rule if it becomes

available. (For additional information on our methodology for determining the LTCH total CCR ceiling, we refer readers to the FY 2007 IPPS final rule (71 FR 48118 through 48119).)

c. Proposed LTCH Statewide Average CCRs

Our general methodology for determining the statewide average CCRs used under the LTCH PPS is similar to our established methodology for determining the LTCH total CCR ceiling because it is based on ''total'' IPPS CCR data. (For additional information on our methodology for determining statewide average CCRs under the LTCH PPS, we refer readers to the FY 2007 IPPS final rule (71 FR 48119 through 48120).) Under the LTCH PPS HCO policy for cases paid under either payment rate at § 412.525(a)(4)(iv)(C)(*2*), the current SSO policy at § 412.529(f)(4)(iii)(B), and the site neutral payment rate at § 412.522(c)(1)(ii), the MAC may use a statewide average CCR, which is established annually by CMS, if it is unable to determine an accurate CCR for an LTCH in one of the following circumstances: (1) New LTCHs that have not yet submitted their first Medicare cost report (a new LTCH is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18); (2) LTCHs whose calculated CCR is in excess of the LTCH total CCR ceiling; and (3) other LTCHs for whom data with which to calculate a CCR are not available (for example, missing or faulty data). (Other sources of data that the MAC may consider in determining an LTCH's CCR include data from a different cost reporting period for the LTCH, data from the cost reporting period preceding the period in which the hospital began to be paid as an LTCH (that is, the period of at least 6 months that it was paid as a short-term, acute care hospital), or data from other comparable LTCHs, such as LTCHs in the same chain or in the same region.)

Consistent with our historical practice of using the best available data, in this proposed rule, we are proposing to use our established methodology for determining the LTCH statewide average CCRs, based on the most recent complete IPPS ''total CCR'' data from the December 2019 update of the PSF, as we proposed, we are proposing to establish LTCH PPS statewide average total CCRs for urban and rural hospitals that will be effective for discharges occurring on or after October 1, 2020, through September 30, 2021, in Table 8C listed in section VI. of the Addendum to this proposed rule (and available via the internet on the CMS website). Consistent with our historical practice, we are proposing to use more recent data to determine the LTCH PPS statewide average total CCRs for FY 2021 proposed rule if it becomes available.

Under the current LTCH PPS labor market areas, all areas in Delaware, the District of Columbia, New Jersey, and Rhode Island are classified as urban. Therefore, there are no rural statewide average total CCRs listed for those jurisdictions in Table 8C. This policy is consistent with the policy that we established when we revised our methodology for determining the applicable LTCH statewide average CCRs in the FY 2007 IPPS final rule (71 FR 48119 through 48121) and is the same as the policy applied under the IPPS. In addition, although Connecticut and Nevada have areas that are designated as rural, in our calculation of the LTCH statewide average CCRs, there was no data available from short-term, acute care IPPS hospitals to compute a rural statewide average CCR or there were no short-term, acute care IPPS hospitals or LTCHs located in these areas as of December 2019. Therefore, consistent with our existing methodology, we are proposing to use the national average total CCR for rural IPPS hospitals for rural Connecticut and Nevada in Table 8C. Furthermore, consistent with our existing methodology, in determining the proposed urban and rural statewide average total CCRs for Maryland LTCHs paid under the LTCH PPS, we are proposing to continue to use, as a proxy, the national average total CCR for urban IPPS hospitals and the national average total CCR for rural IPPS hospitals, respectively. We are proposing to use this proxy because we believe that the CCR data in the PSF for Maryland hospitals may not be entirely accurate (as discussed in greater detail in the FY 2007 IPPS final rule (71 FR 48120)).

d. Reconciliation of HCO Payments

Under the HCO policy for cases paid under either payment rate at § 412.525(a)(4)(iv)(D), the payments for HCO cases are subject to reconciliation. Specifically, any such payments are reconciled at settlement based on the CCR that was calculated based on the cost report coinciding with the discharge. For additional information on the reconciliation policy, we refer readers to Sections 150.26 through 150.28 of the Medicare Claims Processing Manual (Pub. 100–4), as added by Change Request 7192 (Transmittal 2111; December 3, 2010), and the RY 2009 LTCH PPS final rule (73 FR 26820 through 26821).

3. Proposed High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

a. Proposed Changes to High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

Under the regulations at § 412.525(a)(2)(ii) and as required by section 1886(m)(7) of the Act, the fixed-loss amount for HCO payments is set each year so that the estimated aggregate HCO payments for LTCH PPS standard Federal payment rate cases are 99.6875 percent of 8 percent (that is, 7.975 percent) of estimated aggregate LTCH PPS payments for LTCH PPS standard Federal payment rate cases. (For more details on the requirements for high-cost outlier payments in FY 2018 and subsequent years under section 1886(m)(7) of the Act and additional information regarding high-cost outlier payments prior to FY 2018, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38542 through 38544).)

b. Proposed Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2021

When we implemented the LTCH PPS, we established a fixed-loss amount so that total estimated outlier payments are projected to equal 8 percent of total estimated payments under the LTCH PPS (67 FR 56022 through 56026). When we implemented the dual rate LTCH PPS payment structure beginning in FY 2016, we established that, in general, the historical LTCH PPS HCO policy would continue to apply to LTCH PPS standard Federal payment rate cases. That is, the fixed-loss amount and target for LTCH PPS standard Federal payment rate cases would be determined using the LTCH PPS HCO policy adopted when the LTCH PPS was first implemented, but we limited the data used under that policy to LTCH cases that would have been LTCH PPS standard Federal payment rate cases if the statutory changes had been in effect at the time of those discharges.

To determine the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases, we estimate outlier payments and total LTCH PPS payments for each LTCH PPS standard Federal payment rate case (or for each case that would have been a LTCH PPS standard Federal payment rate case if the statutory changes had been in effect at the time of the discharge) using claims data from the MedPAR files. In accordance with § 412.525(a)(2)(ii), the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases results in estimated total outlier payments being projected to be equal to 7.975 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases. We use MedPAR claims data and CCRs based on data from the most recent PSF (or from the applicable statewide average CCR if an LTCH's CCR data are faulty or unavailable) to establish an applicable fixed-loss threshold amount for LTCH PPS standard Federal payment rate cases.

In this proposed rule we are proposing to continue to use our current methodology to calculate an applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2021 using the best available data that would maintain estimated HCO payments at the projected 7.975 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases (based on the payment rates and policies for these cases presented in the proposed rule).

Specifically, based on the most recent complete LTCH data available at this time (that is, LTCH claims data from the December 2019 update of the FY 2019 MedPAR file and CCRs from the December 2019 update of the PSF), we are proposing to determine a proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2021 of $30,515 that would result in estimated outlier payments projected to be equal to 7.975 percent of estimated FY 2021 payments for such cases. We are proposing to continue to make an additional HCO payment for the cost of an LTCH PPS standard Federal payment rate case that exceeds the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the proposed adjusted LTCH PPS standard Federal payment rate payment and the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases of $30,515).

Consistent with our historical practice of using the best data available, when

determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2021 in the proposed rule, we are proposing to use the most recent available LTCH claims data and CCR data.

4. Proposed High-Cost Outlier Payments for Site Neutral Payment Rate Cases

When we implemented the application of the site neutral payment rate in FY 2016, in examining the appropriate fixed-loss amount for site neutral payment rate cases issue, we considered how LTCH discharges based on historical claims data would have been classified under the dual rate LTCH PPS payment structure and the CMS' Office of the Actuary projections regarding how LTCHs will likely respond to our implementation of policies resulting from the statutory payment changes. We again relied on these considerations and actuarial projections in FY 2017 and FY 2018 because the historical claims data available in each of these years were not all subject to the LTCH PPS dual rate payment system. Similarly, for FY 2019 and FY 2020, we continued to rely on these considerations and actuarial projections because, due to the transitional blended payment policy for site neutral payment rate cases, FY 2018 and FY 2019 claims for these cases were not subject to the full effect of the site neutral payment rate.

For FYs 2016 through 2020, at that time our actuaries projected that the proportion of cases that would qualify as LTCH PPS standard Federal payment rate cases versus site neutral payment rate cases under the statutory provisions would remain consistent with what is reflected in the historical LTCH PPS claims data. Although our actuaries did not project an immediate change in the proportions found in the historical data, they did project cost and resource changes to account for the lower payment rates. Our actuaries also projected that the costs and resource use for cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and would likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what is found based on the historical data. As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49619), this actuarial assumption is based on our expectation that site neutral payment rate cases would generally be paid based on an IPPS comparable per diem amount under the statutory LTCH PPS payment changes that began in FY 2016, which, in the majority of cases, is much lower than the payment that would have been paid if these statutory changes were not enacted. In light of these projections and expectations, we discussed that we believed that the use of a single fixed-loss amount and HCO target for all LTCH PPS cases would be problematic. In addition, we discussed that we did not believe that it would be appropriate for comparable LTCH PPS site neutral payment rate cases to receive dramatically different HCO payments from those cases that would be paid under the IPPS (80 FR 49617 through 49619 and 81 FR 57305 through 57307). For those reasons, we stated that we believed that the most appropriate fixed-loss amount for site neutral payment rate cases for FYs 2016 through 2020 would be equal to the IPPS fixed-loss amount for that particular fiscal year. Therefore, we established the fixed-loss amount for site neutral payment rate cases as the corresponding IPPS fixed-loss amounts for FYs 2016 through 2020. In particular, in FY 2020, we established the fixed-loss amount for site neutral payment rate cases as the FY 2019 IPPS fixed-loss amount of $26,552 (as corrected at 84 FR 49845).

As noted earlier, because not all claims in the data used for this FY 2021 IPPS/LTCH PPS proposed rule were subject to the unblended site neutral payment rate, we continue to rely on the same considerations and actuarial projections used in FYs 2016 through 2020 when developing a fixed-loss amount for site neutral payment rate cases for FY 2021. Our actuaries continue to project that site neutral payment rate cases in FY 2021 will continue to mirror an IPPS case paid under the same MS–DRG. That is, our actuaries continue to project that the costs and resource use for FY 2021 cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what was found based on the historical data. (Based on the most recent FY 2019 LTCH claims data used in the development of this FY 2021 IPPS/LTCH PPS proposed rule, approximately 75 percent of LTCH cases were paid the LTCH PPS standard Federal payment rate and approximately 25 percent of LTCH cases were paid the site neutral payment rate for discharges occurring in FY 2019.)

For these reasons, we continue to believe that the most appropriate fixed-loss amount for site neutral payment rate cases for FY 2021 is the IPPS fixed-loss amount for FY 2021. Therefore, consistent with past practice, we are proposing that the applicable HCO threshold for site neutral payment rate cases is the sum of the site neutral payment rate for the case and the IPPS fixed-loss amount. That is, we proposed a fixed-loss amount for site neutral payment rate cases of $30,006. Accordingly, for FY 2021, we propose to calculate a HCO payment for site neutral payment rate cases with costs that exceed the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the site neutral payment rate payment and the proposed fixed-loss amount for site neutral payment rate cases of $30,006).

In establishing a HCO policy for site neutral payment rate cases, we established a budget neutrality adjustment under § 412.522(c)(2)(i). We established this requirement because we believed, and continue to believe, that the HCO policy for site neutral payment rate cases should be budget neutral, just as the HCO policy for LTCH PPS standard Federal payment rate cases is budget neutral, meaning that estimated site neutral payment rate HCO payments should not result in any change in estimated aggregate LTCH PPS payments.

To ensure that estimated HCO payments payable to site neutral payment rate cases in FY 2021 would not result in any increase in estimated aggregate FY 2021 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce site neutral payment rate payments by 5.1 percent to account for the estimated additional HCO payments payable to those cases in FY 2021, in general, we propose to continue this policy.

As discussed earlier, consistent with the IPPS HCO payment threshold, we estimate our fixed-loss threshold of $30,006 results in HCO payments for site neutral payment rate cases to equal 5.1 percent of the site neutral payment rate payments that are based on the IPPS comparable per diem amount. As such, to ensure estimated HCO payments payable for site neutral payment rate cases in FY 2021 would not result in any increase in estimated aggregate FY 2021 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce the site neutral payment rate amount paid under § 412.522(c)(1)(i) by 5.1 percent to account for the estimated additional HCO payments payable for site neutral payment rate cases in FY 2021. In order to achieve this, for FY 2021, we are proposing to apply a budget neutrality factor of 0.949 (that is, the decimal equivalent of a 5.1 percent reduction, determined as $1.0 - 5.1/100 = 0.949$) to the site neutral payment rate for those site neutral payment rate cases paid under § 412.522(c)(1)(i). We note that, consistent with our current policy, this proposed HCO budget neutrality adjustment would not be applied to the HCO portion of the site neutral payment rate amount (81 FR 57309).

E. Proposed Update to the IPPS Comparable Amount To Reflect the Statutory Changes to the IPPS DSH Payment Adjustment Methodology

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50766), we established a policy to reflect the changes to the Medicare IPPS DSH payment adjustment methodology made by section 3133 of the Affordable Care Act in the calculation of the ''IPPS comparable amount'' under the SSO policy at § 412.529 and the ''IPPS equivalent amount'' under the site neutral payment rate at § 412.522. Historically, the determination of both the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' includes an amount for inpatient operating costs ''for the costs of serving a disproportionate share of low-income patients.'' Under the statutory changes to the Medicare DSH payment adjustment methodology that began in FY 2014, in general, eligible IPPS hospitals receive an empirically justified Medicare DSH payment equal to 25 percent of the amount they otherwise would have received under the statutory formula for Medicare DSH payments prior to the amendments made by the Affordable Care Act. The remaining amount, equal to an estimate of 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage

of individuals who are uninsured and any additional statutory adjustment, is made available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The additional uncompensated care payments are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all IPPS hospitals that receive Medicare DSH payments.

To reflect the statutory changes to the Medicare DSH payment adjustment methodology in the calculation of the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS, we stated that we will include a reduced Medicare DSH payment amount that reflects the projected percentage of the payment amount calculated based on the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act that will be paid to eligible IPPS hospitals as empirically justified Medicare DSH payments and uncompensated care payments in that year (that is, a percentage of the operating Medicare DSH payment amount that has historically been reflected in the LTCH PPS payments that are based on IPPS rates). We also stated that the projected percentage will be updated annually, consistent with the annual determination of the amount of uncompensated care payments that will be made to eligible IPPS hospitals. We believe that this approach results in appropriate payments under the LTCH PPS and is consistent with our intention that the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS closely resemble what an IPPS payment would have been for the same episode of care, while recognizing that some features of the IPPS cannot be translated directly into the LTCH PPS (79 FR 50766 through 50767).

For FY 2021, as discussed in greater detail in section IV.G.3. of the preamble of this proposed rule, based on the most recent data available, our estimate of 75 percent of the amount that would otherwise have been paid as Medicare DSH payments (under the methodology outlined in section 1886(r)(2) of the Act) is adjusted to 67.86 percent of that amount to reflect the change in the percentage of individuals who are uninsured. The resulting amount is then used to determine the proposed amount available to make uncompensated care payments to eligible IPPS hospitals in FY 2021. In other words, the amount of the Medicare DSH payments that would have been made prior to the amendments made by the Affordable Care Act is adjusted to 50.90 percent (the product of 75 percent and 67.86 percent) and the resulting amount is used to calculate the uncompensated care payments to eligible hospitals. As a result, for FY 2021, we project that the reduction in the amount of Medicare DSH payments pursuant to section 1886(r)(1) of the Act, along with the payments for uncompensated care under section 1886(r)(2) of the Act, will result in overall Medicare DSH payments of 75.90 percent of the amount of Medicare DSH payments that would otherwise have been made in the absence of the amendments made by the Affordable Care Act (that is, 25 percent + 50.90 percent = 75.90 percent).

Therefore, for FY 2021, we are proposing to establish that the calculation of the ''IPPS comparable amount'' under § 412.529 would include an applicable operating Medicare DSH payment amount that is equal to 75.90 percent of the operating Medicare DSH payment amount that would have been paid based on the statutory Medicare DSH payment formula absent the amendments made by the Affordable Care Act. Furthermore, consistent with our historical practice, we are proposing that, if more recent data became available, we would use that data to determine this factor in the final rule.

F. Computing the Proposed Adjusted LTCH PPS Federal Prospective Payments for FY 2021

Section 412.525 sets forth the adjustments to the LTCH PPS standard Federal payment rate. Under the dual rate LTCH PPS payment structure, only LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate. Under § 412.525(c), the LTCH PPS standard Federal payment rate is adjusted to account for differences in area wages by multiplying the labor-related share of the LTCH PPS standard Federal payment rate for a case by the applicable LTCH PPS wage index (the FY 2020 values are shown in Tables 12A through 12B listed in section VI. of the Addendum to this proposed rule and are available via the internet on the CMS website). The LTCH PPS standard Federal payment rate is also adjusted to account for the higher costs of LTCHs located in Alaska and Hawaii by the applicable COLA factors (the proposed FY 2021 factors are shown in the chart in section V.C. of this Addendum) in accordance with § 412.525(b). In this proposed rule, we are proposing to establish an LTCH PPS standard Federal payment rate for FY 2021 of $43,849.28, as discussed in section V.A. of the Addendum to this proposed rule. We illustrate the methodology to adjust the proposed LTCH PPS standard Federal payment rate for FY 2021 in the following example:

Example: During FY 2021, a Medicare discharge that meets the criteria to be excluded from the site neutral payment rate, that is, an LTCH PPS standard Federal payment rate case, is from an LTCH that is located in CBSA 16984, which has a proposed FY 2021 LTCH PPS wage index value of 1.0328 (obtained from Table 12A listed in section VI. of the Addendum to this proposed rule and available via the internet on the CMS website). The Medicare patient case is classified into MS–LTC–DRG 189 (Pulmonary Edema & Respiratory Failure), which has a proposed relative weight for FY 2021 of 0.9451 (obtained from Table 11 listed in section VI. of the Addendum to this proposed rule and available via the internet on the CMS website). The LTCH submitted quality reporting data for FY 2021 in accordance with the LTCH QRP under section 1886(m)(5) of the Act.

To calculate the LTCH's total adjusted proposed Federal prospective payment for this Medicare patient case in FY 2021, we computed the wage-adjusted Federal prospective payment amount by multiplying the unadjusted FY 2021 LTCH PPS standard Federal payment rate ($43,849.28) by the labor-related share (0.680 percent) and the wage index value (1.0328). This wage-adjusted amount was then added to the nonlabor-related portion of the unadjusted LTCH PPS standard Federal payment rate (0.320 percent; adjusted for cost of living, if applicable) to determine the adjusted LTCH PPS standard Federal payment rate, which is then multiplied by the MS–LTC–DRG relative weight (0.9451) to calculate the total adjusted LTCH PPS standard Federal prospective payment for FY 2021 ($42,366.27). The table illustrates the components of the calculations in this example.

Unadjusted LTCH PPS Standard Federal Prospective Payment Rate	$43,849.28
Labor-Related Share	x 0.680
Labor-Related Portion of the LTCH PPS Standard Federal Payment Rate	= $29,817.51
Wage Index (CBSA 16984)	x 1.0328
Wage-Adjusted Labor Share of the LTCH PPS Standard Federal Payment Rate	= $30,795.52
Nonlabor-Related Portion of the LTCH PPS Standard Federal Payment Rate ($43,849.28 x 0.320)	+ $14,031.77
Adjusted LTCH PPS Standard Federal Payment Amount	= $44,827.29
MS-LTC-DRG 189 Relative Weight	x 0.9451
Total Adjusted LTCH PPS Standard Federal Prospective Payment	= $42,366.27

VI. Tables Referenced in This Proposed Rule Generally Available Through the Internet on the CMS Website

This section lists the tables referred to throughout the preamble of this proposed rule and in the Addendum. In the past, a majority of these tables were published in the **Federal Register** as part of the annual proposed and final rules. However, similar to FYs 2012 through 2020, for the FY 2021 rulemaking cycle, the IPPS and LTCH PPS tables will not be published in the **Federal Register** in the annual IPPS/LTCH PPS proposed and final rules and will be available through the internet. Specifically, all IPPS tables listed in this section, with the exception of IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E, will generally be available through the internet. IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E are displayed at the end of this section and will continue to be published in the **Federal Register** as part of the annual proposed and final rules. For additional discussion of the information included in the IPPS and LTCH PPS tables associated with the IPPS/LTCH PPS proposed and final rules, as well as prior changes to the information included in these tables, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41739 through 41740). In addition, under the HAC Reduction Program, established by section 3008 of the Affordable Care Act, a hospital's total payment may be reduced by 1 percent if it is in the lowest HAC performance quartile. The hospital level-data for the FY 2021 HAC Reduction Program will be made publicly available once it has undergone the review and corrections process.

As with FY 2020 IPPS/LTCH PPS proposed and final rules, we are no longer including Table 15, which had typically included the fiscal year readmissions payment adjustment factors because hospitals have not yet had the opportunity to review and correct the data before the data are made public under our policy regarding the reporting of hospital-specific data. After hospitals have been given an opportunity to review and correct their calculations for FY 2021, we will post Table 15 (which will be available via the internet on the CMS website) to display the final FY 2021 readmissions payment adjustment factors that will be applicable to discharges occurring on or after October 1, 2020. We expect Table 15 will be posted on the CMS website in the fall of 2020.

Readers who experience any problems accessing any of the tables that are posted on the CMS websites identified in this section should contact Michael Treitel at (410) 786–4552. The following IPPS tables for this proposed rule are generally available through 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 2021 IPPS Proposed Rule Home Page'' or ''Acute Inpatient-Files-for Download.''

Table 2.—Proposed Case-Mix Index and Wage Index Table by CCN—FY 2021
Table 3.—Proposed Wage Index Table by CBSA—FY 2021
Table 4A.—Proposed List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act—FY 2021
Table 4B.—Proposed Counties Redesignated under Section 1886(d)(8)(B) of the Act (LUGAR COUNTIES)—FY 2021
Table 5.—Proposed List of Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2021
Table 6A.—New Diagnosis Codes—FY 2021
Table 6B.—New Procedure Codes—FY 2021
Table 6C.—Invalid Diagnosis Codes—FY 2021
Table 6E.—Revised Diagnosis Code Titles—FY 2021
Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2021
Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2021
Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2021
Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2021
Table 6I.1.—Proposed Additions to the MCC List—FY 2021
Table 6I.2.—Proposed Deletions to the MCC List—FY 2021
Table 6J.1.—Proposed Additions to the CC List—FY 2021
Table 6J.2.—Proposed Deletions to the CC List—FY 2021
Table 6P.—ICD–10–CM and ICD–10–PCS Codes for Proposed MS–DRG Changes—FY 2021 (Table 6P contains multiple tables, 6P.1a. through 6P.4a., that include the ICD–10–CM and ICD–10–PCS code lists relating to proposed specific MS–DRG changes. These tables are referred to throughout section II.D. of the preamble of this proposed rule.)
Table 7A.—Proposed Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2019 MedPAR Update—December 2019 GROUPER Version 37 MS–DRGs
Table 7B.—Proposed Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2019 MedPAR Update—December 2019 GROUPER Version 38 MS–DRGs
Table 8A.—Proposed FY 2021 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)
Table 8B.—Proposed FY 2021 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals
Table 16.—Proxy Hospital Value-Based Purchasing (VBP) Program Adjustment Factors for FY 2021
Table 18.—Proposed FY 2021 Medicare DSH Uncompensated Care Payment Factor 3

The following LTCH PPS tables for this FY 2021 proposed rule are available through the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1735–P:

Table 8C.—Proposed FY 2021 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural)
Table 11.—Proposed MS–LTC–DRGs, Relative Weights, Geometric Average Length of Stay, and Short-Stay Outlier (SSO) Threshold for LTCH PPS Discharges Occurring from October 1, 2020 through September 30, 2021
Table 12A.—Proposed LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2020 through September 30, 2021
Table 12B.—Proposed LTCH PPS Wage Index for Rural Areas for Discharges Occurring from October 1, 2020 through September 30, 2021

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TABLE 1A.—PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (68.3 PERCENT LABOR SHARE/31.7 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)--FY 2021

Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 2.6 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0.35 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.85 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.4 Percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$4,084.16	$1,895.58	$3,994.60	$1,854.01	$4,054.31	$1,881.72	$3,964.74	$1,840.15

TABLE 1B.—PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1)—FY 2021

Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 2.6 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0.35 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.85 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.4 Percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,707.44	$2,272.30	$3,626.14	$2,222.47	$3,680.34	$2,255.69	$3,599.03	$2,205.86

TABLE 1C.—PROPOSED ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR HOSPITALS IN PUERTO RICO, LABOR/NONLABOR (NATIONAL: 62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE BECAUSE WAGE INDEX IS LESS THAN OR EQUAL TO 1);—FY 2021

	Rates if Wage Index is Greater Than 1		Rates if Wage Index is Less Than or Equal to 1	
Standardized Amount	Labor	Nonlabor	Labor	Nonlabor
National[1]	Not Applicable	Not Applicable	$3,707.44	$2,272.30

[1] For FY 2021, there are no CBSAs in Puerto Rico with a national wage index greater than 1.

TABLE 1D.—PROPOSED CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2021

	Rate
National	$468.36

TABLE 1E.—PROPOSED LTCH PPS STANDARD FEDERAL PAYMENT RATE--FY 2021

	Full Update (2.5 Percent)	Reduced Update* (0.5 Percent)
Standard Federal Rate	$43,849.28	$42,993.68

* For LTCHs that fail to submit quality reporting data for FY 2021 in accordance with the LTCH Quality Reporting Program (LTCH QRP), the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

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Appendix A: Economic Analyses

I. Regulatory Impact Analysis

A. Statement of Need

This proposed rule is necessary in order to make payment and policy changes under the Medicare IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This proposed rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS. Also as we note later in this Appendix, the primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the proposed changes in this proposed rule, such as the proposed updates to the IPPS and LTCH PPS rates, and the proposals and discussions relating to applications for new technology add-on payments, are needed to further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries.

For example, without additional payments for new medical technologies that meet the criteria for approval for new technology add-on payments, Medicare beneficiaries may not have appropriate access to these new technologies. We discuss the technologies for which we received applications for add-on payments for new medical technologies for FY 2021 in sections II.G.5. and 6. of the preamble to this proposed rule. As discussed in section II.G.6. of the preamble of this proposed rule, under the alternative pathway for new technology add-on payments, new technologies that are medical products with a Qualified Infectious Disease Product (QIDP) designation or are part of the Breakthrough Device program will be considered new and not substantially similar to an existing technology and will not need to demonstrate that the technology represents a substantial clinical improvement. These technologies must still meet the cost criterion.

We are proposing to approve nine alternative pathway applicant technologies (three Breakthrough devices and six QIDPs) for FY 2021 based our analysis of the cost criterion. We have not yet determined whether any of the 15 technologies under the traditional pathway discussed in section II.G.5. of the preamble of this proposed rule will meet the criteria for new technology add-on payments for FY 2021. Those determinations will be made in the final rule following a review of the comments received.

We expect that the proposals in this proposed rule would ensure that the outcomes of the prospective payment systems are reasonable and equitable, while avoiding or minimizing unintended adverse consequences.

B. Overall Impact

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), the Congressional Review Act (5 U.S.C. 804(2), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

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.

We have determined that this proposed rule is a major rule as defined in 5 U.S.C. 804(2). We estimate that the proposed changes for FY 2021 acute care hospital operating and capital payments would redistribute amounts in excess of $100 million to acute care hospitals. The proposed applicable percentage increase to the IPPS rates required by the statute, in conjunction with other proposed payment changes in this proposed rule, would result in an estimated $2.07 billion increase in FY 2021 payments, primarily driven by a combined $1.98 billion increase in FY 2021 operating payments and uncompensated care payments, and a net increase of $89 million resulting from estimated changes in FY 2021 capital payments and new technology add-on payments. These proposed changes are relative to payments made in FY 2020. The impact analysis of the capital payments can be found in section I.I. of this Appendix. In addition, as described in section I.J. of this Appendix, LTCHs are expected to experience a decrease in payments by approximately 36 million in FY 2021 relative to FY 2020, primarily due to the end of the statutory transition period for site neutral payment rate cases.

Our operating impact estimate includes the proposed 0.5 percentage point adjustment required under section 414 of the MACRA applied to the IPPS standardized amount, as discussed in section II.D. of the preamble of this proposed rule. In addition, our operating payment impact estimate includes the proposed 2.6 percent hospital update to the standardized amount (which includes the estimated 3.0 percent market basket update less the proposed 0.4 percentage point for the multifactor productivity (MFP) adjustment). The estimates of IPPS operating payments to acute care hospitals do not reflect any changes in hospital admissions or real case-mix intensity, which will also affect overall payment changes.

The analysis in this Appendix, in conjunction with the remainder of this document, demonstrates that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. This proposed rule would affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant. Finally, in accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget has reviewed this proposed rule.

C. Objectives of the IPPS and the LTCH PPS

The primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the proposed changes in this proposed rule would further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these proposed changes would ensure that the outcomes of the prospective payment systems are reasonable and equitable, while avoiding or minimizing unintended adverse consequences.

Because this proposed rule contains a range of policies, we refer readers to the section of the proposed rule where each policy is discussed. These sections include the rationale for our decisions, including the need for the proposed policy.

D. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our proposed policy changes, as well as statutory changes effective for FY 2021, on various hospital groups. We estimate the effects of individual proposed policy changes by estimating payments per case, while holding all other payment policies constant. We use the best data available, but, generally unless specifically indicated, we do not attempt to make adjustments for future changes in such variables as admissions, lengths of stay, case-mix, changes to the Medicare population, or incentives. In addition, we discuss limitations of our analysis for specific proposed policies in the discussion of those proposed policies as needed.

E. Hospitals Included in and Excluded From the IPPS

The prospective payment systems for hospital inpatient operating and capital-related costs of acute care hospitals encompass most general short-term, acute care hospitals that participate in the Medicare program. There were 27 Indian Health Service hospitals in our database, which we excluded from the analysis due to the special characteristics of the prospective payment methodology for these hospitals. Among other short-term, acute care hospitals, hospitals in Maryland are paid in accordance with the Maryland Total Cost of Care Model, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, 6 short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling.

As of March 2020, there were 3,199 IPPS acute care hospitals included in our analysis. This represents approximately 54 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,414 CAHs. These small, limited service hospitals are paid on the basis of reasonable costs, rather than under the IPPS. IPPS-excluded hospitals and units, which are paid under separate payment systems, include IPFs, IRFs, LTCHs, RNHCIs, children's hospitals, 11 cancer hospitals, 1 extended neoplastic disease care hospital, and 6 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. Changes in the prospective payment systems for IPFs and IRFs are made through separate rulemaking. Payment impacts of proposed changes to the prospective payment systems for these IPPS-excluded hospitals and units are not included in this proposed rule. The impact of the proposed update and policy changes to the LTCH PPS for FY 2021 is discussed in section I.J. of this Appendix.

F. Effects on Hospitals and Hospital Units Excluded From the IPPS

As of March 2020, there were 95 children's hospitals, 11 cancer hospitals, 6 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa, 1 extended neoplastic disease care hospital, and 15 RNHCIs being paid on a reasonable cost basis subject to the rate-of-increase ceiling under § 413.40. (In accordance with § 403.752(a) of the regulation, RNHCIs are paid under § 413.40.) Among the remaining providers, 302 rehabilitation hospitals and 815 rehabilitation units, and approximately 360 LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and 549 psychiatric hospitals and 1,016 psychiatric units are paid the Federal per diem amount under the IPF PPS. As stated previously, IRFs and IPFs are not affected by the proposed rate updates discussed in this proposed rule. The impacts of the proposed changes on LTCHs are discussed in section I.J. of this Appendix.

For children's hospitals, the 11 cancer hospitals, the 6 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, the 1 extended neoplastic disease care hospital, and RNHCIs, the proposed update of the rate-of-increase limit (or target amount) is the estimated FY 2021 percentage increase in the 2014-based IPPS operating market basket, consistent with section 1886(b)(3)(B)(ii) of the Act, and §§ 403.752(a) and 413.40 of the regulations. Consistent with current law, based on IGI's fourth quarter 2019 forecast of the 2014-based IPPS market basket increase, we are estimating the proposed FY 2021 update to be 3.0 percent (that is, the estimate of the market basket rate-of-increase). We are proposing that if more recent data become available for the final rule, we would use such data, if appropriate, to calculate the IPPS operating market basket update for FY 2021. However, the Affordable Care Act requires an adjustment for multifactor productivity (proposed 0.4 percentage point for FY 2021), resulting in a proposed 2.6 percent applicable percentage increase for IPPS hospitals that submit quality data and are meaningful EHR users, as discussed in section IV.B. of the preamble of this proposed rule. Children's hospitals, the 11 cancer hospitals, the 6 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, the 1 extended neoplastic disease care hospital, and RNHCIs that continue to be paid based on reasonable costs subject to rate-of-increase limits under § 413.40 of the regulations are not subject to the reductions in the applicable percentage increase required under the Affordable Care Act. Therefore, for those hospitals paid under § 413.40 of the regulations, the proposed update is the percentage increase in the 2014-based IPPS operating market basket for FY 2021, estimated at 3.0 percent

The impact of the proposed update in the rate-of-increase limit on those excluded hospitals depends on the cumulative cost increases experienced by each excluded hospital since its applicable base period. For excluded hospitals that have maintained their cost increases at a level below the rate-of-increase limits since their base period, the major effect is on the level of incentive payments these excluded hospitals receive. Conversely, for excluded hospitals with cost increases above the cumulative update in their rate-of-increase limits, the major effect is the amount of excess costs that would not be paid.

We note that, under § 413.40(d)(3), an excluded hospital that continues to be paid under the TEFRA system and whose costs exceed 110 percent of its rate-of-increase limit receives its rate-of-increase limit plus the lesser of: (1) 50 percent of its reasonable costs in excess of 110 percent of the limit; or (2) 10 percent of its limit. In addition, under the various provisions set forth in § 413.40, hospitals can obtain payment adjustments for justifiable increases in operating costs that exceed the limit.

G. Quantitative Effects of the Proposed Policy Changes Under the IPPS for Operating Costs

1. Basis and Methodology of Estimates

In this proposed rule, we are announcing proposed policy changes and payment rate updates for the IPPS for FY 2021 for operating costs of acute care hospitals. The proposed FY 2021 updates to the capital payments to acute care hospitals are discussed in section I.I. of this Appendix.

Based on the overall proposed percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2021 operating payments would increase by 2.5 percent, compared to FY 2020. In addition to the proposed applicable percentage increase, this amount reflects the proposed +0.5 percentage point permanent adjustment to the standardized amount required under section 414 of MACRA. The impacts do not reflect changes in the number of hospital admissions or real case-mix intensity, which would also affect overall payment changes.

We have prepared separate impact analyses of the proposed changes to each system. This section deals with the proposed changes to the operating inpatient prospective payment system for acute care hospitals. Our payment simulation model relies on the most recent

available claims data to enable us to estimate the impacts on payments per case of certain proposed changes in this proposed rule. However, there are other proposed changes for which we do not have data available that would allow us to estimate the payment impacts using this model. For those proposed changes, we have attempted to predict the payment impacts based upon our experience and other more limited data.

The data used in developing the quantitative analyses of proposed changes in payments per case presented in this section are taken from the FY 2019 MedPAR file and the most current Provider-Specific File (PSF) that are used for payment purposes. Although the analyses of the proposed changes to the operating PPS do not incorporate cost data, data from the most recently available hospital cost reports were used to categorize hospitals. Our analysis has several qualifications. First, in this analysis, we do not make adjustments for future changes in such variables as admissions, lengths of stay, or underlying growth in real case-mix. Second, due to the interdependent nature of the IPPS payment components, it is very difficult to precisely quantify the impact associated with each proposed change. Third, we use various data sources to categorize hospitals in the tables. In some cases, particularly the number of beds, there is a fair degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. However, for individual hospitals, some miscategorizations are possible.

Using cases from the FY 2019 MedPAR file, we simulate payments under the operating IPPS given various combinations of payment parameters. As described previously, Indian Health Service hospitals and hospitals in Maryland were excluded from the simulations. The impact of proposed payments under the capital IPPS, and the impact of proposed payments for costs other than inpatient operating costs, are not analyzed in this section. Estimated payment impacts of the capital IPPS for FY 2021 are discussed in section I.I. of this Appendix.

We discuss the following proposed changes:

- The effects of the application of the proposed applicable percentage increase of 2.6 percent (that is, a 3.0 percent market basket update with a proposed reduction of 0.4 percentage point for the multifactor productivity adjustment), and a proposed 0.5 percentage point adjustment required under section 414 of the MACRA to the IPPS standardized amount, and the proposed applicable percentage increase (including the market basket update and the proposed multifactor productivity adjustment) to the hospital-specific rates.
- The effects of the proposed changes to the relative weights and MS–DRG GROUPER.
- The effects of the proposed changes in hospitals' wage index values reflecting updated wage data from hospitals' cost reporting periods beginning during FY 2017, compared to the FY 2016 wage data, to calculate the proposed FY 2021 wage index.
- The effects of the geographic reclassifications by the MGCRB (as of publication of this proposed rule) that will be effective for FY 2021.
- The effects of the proposed rural floor with the application of the national budget neutrality factor to the wage index.
- The effects of the proposed frontier State wage index adjustment under the statutory provision that requires hospitals located in States that qualify as frontier States to not have a wage index less than 1.0. This provision is not budget neutral.
- The effects of the implementation of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes for FY 2021. This provision is not budget neutral.
- The effects of the wage index including our proposed adoption of the revised labor market area delineations in OMB Bulletin No. 18–04 and the effects of the proposed transition to apply a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index from the prior fiscal year.
- The total estimated change in payments based on the proposed FY 2021 policies relative to payments based on FY 2020 policies, including estimated changes in outlier payments.

To illustrate the impact of the proposed FY 2021 changes, our analysis begins with a FY 2020 baseline simulation model using: the FY 2020 applicable percentage increase of 2.6 percent; the 0.5 percentage point adjustment required under section 414 of the MACRA applied to the IPPS standardized amount; the FY 2020 MS–DRG GROUPER (Version 37); the FY 2020 CBSA designations for hospitals based on the OMB definitions from the 2010 Census; the FY 2020 wage index; and no MGCRB reclassifications. Outlier payments are set at 5.1 percent of total operating MS–DRG and outlier payments for modeling purposes.

Section 1886(b)(3)(B)(viii) of the Act, as added by section 5001(a) of Public Law 109–171, as amended by section 4102(b)(1)(A) of the ARRA (Pub. L. 111–5) and by section 3401(a)(2) of the Affordable Care Act (Pub. L. 111–148), provides that, for FY 2007 and each subsequent year through FY 2014, the update factor will include a reduction of 2.0 percentage points for any subsection (d) hospital that does not submit data on measures in a form and manner, and at a time specified by the Secretary. Beginning in FY 2015, the reduction is one-quarter of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act, or one-quarter of the market basket update. Therefore, as discussed in section IV.B.1. of the preamble of this proposed rule, for FY 2021, we are proposing that hospitals that do not submit quality information under rules established by the Secretary and that are meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act would receive an applicable percentage increase of 1.85 percent. At the time this impact was prepared, 54 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2021 because they failed the quality data submission process or did not choose to participate, but are meaningful EHR users. For purposes of the simulations shown later in this section, we modeled the proposed payment changes for FY 2021 using a reduced update for these hospitals.

For FY 2021, in accordance with section 1886(b)(3)(B)(ix) of the Act, a hospital that has been identified as not a meaningful EHR user will be subject to a reduction of three-quarters of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act. Therefore, as discussed in section IV.B.1. of the preamble of this proposed rule, for FY 2021, we are proposing that hospitals that are identified as not meaningful EHR users and do submit quality information under section 1886(b)(3)(B)(viii) of the Act would receive an applicable percentage increase of 0.35 percent. At the time this impact analysis was prepared, 67 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2021 because they are identified as not meaningful EHR users that do submit quality information under section 1886(b)(3)(B)(viii) of the Act. For purposes of the simulations shown in this section, we modeled the proposed payment changes for FY 2021 using a reduced update for these hospitals.

Hospitals that are identified as not meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act and also do not submit quality data under section 1886(b)(3)(B)(viii) of the Act would receive a proposed applicable percentage increase of −0.4 percent, which reflects a one-quarter reduction of the market basket update for failure to submit quality data and a three-quarter reduction of the market basket update for being identified as not a meaningful EHR user together with the proposed 0.4 percentage point reduction for the multifactor productivity adjustment. At the time this impact was prepared, 14 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2021 because they are identified as not meaningful EHR users that do not submit quality data under section 1886(b)(3)(B)(viii) of the Act.

Each proposed policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2021 model incorporating all of the proposed changes. This simulation allows us to isolate the effects of each change.

Our comparison illustrates the proposed percent change in payments per case from FY 2020 to FY 2021. Two factors not discussed separately have significant impacts here. The first factor is the proposed update to the standardized amount. In accordance with section 1886(b)(3)(B)(i) of the Act, we are proposing to update the standardized amounts for FY 2021 using a proposed applicable percentage increase of 2.6 percent. This includes our forecasted IPPS operating hospital market basket increase of 3.0 percent with a proposed 0.4 percentage point reduction for the multifactor productivity adjustment. Hospitals that fail to comply with the quality data submission requirements and are meaningful EHR users would receive a proposed update of 1.85

percent. This proposed update includes a reduction of one-quarter of the market basket update for failure to submit these data. Hospitals that do comply with the quality data submission requirements but are not meaningful EHR users would receive a proposed update of 0.35 percent, which includes a reduction of three-quarters of the market basket update. Furthermore, hospitals that do not comply with the quality data submission requirements and also are not meaningful EHR users would receive a proposed update of −0.4 percent. Under section 1886(b)(3)(B)(iv) of the Act, the update to the hospital-specific amounts for SCHs and MDHs is also equal to the applicable percentage increase, or 2.6 percent, if the hospital submits quality data and is a meaningful EHR user.

A second significant factor that affects the proposed changes in hospitals' payments per case from FY 2020 to FY 2021 is the change in hospitals' geographic reclassification status from 1 year to the next. That is, payments may be reduced for hospitals reclassified in FY 2020 that are no longer reclassified in FY 2021. Conversely, payments may increase for hospitals not reclassified in FY 2020 that are reclassified in FY 2021.

2. Analysis of Table I

Table I displays the results of our analysis of the proposed changes for FY 2021. The table categorizes hospitals by various geographic and special payment consideration groups to illustrate the varying impacts on different types of hospitals. The top row of the table shows the overall impact on the 3,199 acute care hospitals included in the analysis.

The next four rows of Table I contain hospitals categorized according to their geographic location: All urban, which is further divided into large urban and other urban; and rural. There are 2,459 hospitals located in urban areas and 740 hospitals in rural areas included in our analysis. The next two groupings are by bed-size categories, shown separately for urban and rural hospitals. The last groupings by geographic location are by census divisions, also shown separately for urban and rural hospitals.

The second part of Table I shows hospital groups based on hospitals' FY 2021 payment classifications, including any reclassifications under section 1886(d)(10) of the Act. For example, the rows labeled urban and rural show that the numbers of hospitals paid based on these categorizations after consideration of geographic reclassifications (including reclassifications under sections 1886(d)(8)(B) and 1886(d)(8)(E) of the Act that have implications for capital payments) are 2,028, and 1,171, respectively.

The next three groupings examine the impacts of the proposed changes on hospitals grouped by whether or not they have GME residency programs (teaching hospitals that receive an IME adjustment) or receive Medicare DSH payments, or some combination of these two adjustments. There are 2,043 nonteaching hospitals in our analysis, 901 teaching hospitals with fewer than 100 residents, and 255 teaching hospitals with 100 or more residents.

In the DSH categories, hospitals are grouped according to their DSH payment status, and whether they are considered urban or rural for DSH purposes. The next category groups together hospitals considered urban or rural, in terms of whether they receive the IME adjustment, the DSH adjustment, both, or neither.

The next three rows examine the impacts of the proposed changes on rural hospitals by special payment groups (SCHs, MDHs and RRCs). There were 471 RRCs, 304 SCHs, 146 MDHs, 148 hospitals that are both SCHs and RRCs, and 24 hospitals that are both MDHs and RRCs.

The next series of groupings are based on the type of ownership and the hospital's Medicare utilization expressed as a percent of total inpatient days. These data were taken from the FY 2017 or FY 2016 Medicare cost reports.

The next grouping concerns the geographic reclassification status of hospitals. The first subgrouping is based on whether a hospital is reclassified or not. The second and third subgroupings are based on whether urban and rural hospitals were reclassified by the MGCRB for FY 2021 or not, respectively. The fourth subgrouping displays hospitals that reclassified from urban to rural in accordance with section 1886(d)(8)(E) of the Act. The fifth subgrouping displays hospitals deemed urban in accordance with section 1886(d)(8)(B) of the Act.

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TABLE I.—IMPACT ANALYSIS OF PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2021

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2021 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Proposed FY 2021 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2021 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Proposed Frontier State Wage Index and Proposed Outmigration Adjustment (6)[7]	All Proposed FY 2021 Changes (7)[8]
All Hospitals	3,199	3.1	0	0	0	0	0.1	2.5
By Geographic Location:								
Urban hospitals	2,459	3.1	0	0	-0.1	0	0.1	2.5
Rural hospitals	740	2.8	-0.3	0	1.1	-0.1	0.1	2.3
Bed Size (Urban):								
0-99 beds	634	3	-0.3	-0.1	-0.7	0.1	0.3	2.2
100-199 beds	752	3.1	-0.1	0	-0.1	0.2	0.2	2.5
200-299 beds	438	3.1	-0.1	0	0.2	0	0.2	2.4
300-499 beds	414	3.1	0	-0.1	0	0	0.1	2.5
500 or more beds	221	3	0.2	0.1	-0.2	-0.1	0	2.7
Bed Size (Rural):								
0-49 beds	300	2.8	-0.5	0	0.2	-0.2	0.2	2
50-99 beds	259	2.6	-0.3	0.1	0.8	-0.1	0.2	2.3
100-149 beds	98	2.8	-0.3	0.1	1.2	-0.1	0	2.3
150-199 beds	44	2.9	-0.2	-0.1	1	0	0.2	2.4
200 or more beds	39	2.9	-0.1	-0.1	1.9	-0.2	0	2.4
Urban by Region:								
New England	112	3.1	0.1	-0.9	1.5	2.1	0.1	2.4
Middle Atlantic	305	3.1	0	0.4	0.2	-0.3	0.1	2.7
South Atlantic	402	3.1	0	0.1	-0.5	-0.3	0	2.6
East North Central	380	3.1	0	0	-0.3	-0.3	0	2.5
East South Central	144	3.1	0	0	-0.3	-0.3	0	2.5
West North Central	159	3	0	-0.4	-0.6	-0.3	0.6	2.2
West South Central	364	3.1	0	0.1	-0.4	-0.3	0	2.6
Mountain	172	3	0	-0.4	-0.2	0	0.3	2
Pacific	371	3	0.1	0	0.3	0.6	0.1	2.7
Puerto Rico	50	3.1	0.1	-0.9	-0.9	0.2	0.1	1.9
Rural by Region:								
New England	19	2.9	0	-0.4	0	0.3	0	2.4
Middle Atlantic	50	2.8	-0.3	0.3	1.3	-0.1	0	2.5
South Atlantic	115	2.9	-0.3	0	1.4	-0.2	0	2.1
East North Central	114	2.7	-0.3	0.1	0.9	-0.1	0	2.4
East South Central	144	3	-0.3	-0.1	2	-0.2	0	2.4
West North Central	89	2.6	-0.4	0	-0.1	-0.1	0.3	2.1
West South Central	136	2.9	-0.3	0.1	2	-0.2	0.1	2.3
Mountain	49	2.6	-0.3	-0.2	-0.2	-0.1	1.1	2.1
Pacific	24	2.7	-0.2	0.2	1.1	-0.1	0	2.3

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2021 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Proposed FY 2021 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2021 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Proposed Frontier State Wage Index and Proposed Outmigration Adjustment (6)[7]	All Proposed FY 2021 Changes (7)[8]
By Payment Classification:								
Urban hospitals	2,028	3.1	0	0	-0.5	0	0.1	2.6
Rural areas	1,171	3	0	0	0.8	-0.1	0.1	2.4
Teaching Status:		0	0	0	0	0	0	0
Nonteaching	2,043	3	-0.2	0	0.1	0	0.1	2.3
Fewer than 100 residents	901	3.1	-0.1	0	0	0	0.2	2.5
100 or more residents	255	3	0.3	0	-0.1	-0.1	0.1	2.7
Urban DSH:		0	0	0	0	0	0	0
Non-DSH	505	3.1	-0.1	0.1	-0.4	-0.1	0.2	2.3
100 or more beds	1,273	3.1	0	0	-0.4	0.1	0.1	2.6
Less than 100 beds	352	3.1	-0.3	-0.1	-0.5	0.2	0.2	2.2
Rural DSH:								
SCH	257	2.6	-0.3	0	0.1	-0.1	0.1	2.3
RRC	538	3	0	0	1.1	-0.1	0.1	2.5
100 or more beds	59	3.1	0.1	0	-0.9	-0.3	0.1	1.9
Less than 100 beds	215	3	-0.4	0.1	0.3	-0.3	0.2	2.2
Urban teaching and DSH:								
Both teaching and DSH	738	3.1	0.1	0	-0.5	0	0.1	2.6
Teaching and no DSH	70	3.1	0	0.1	-0.8	-0.2	0.1	2.2
No teaching and DSH	887	3.1	-0.1	-0.1	-0.2	0.3	0.1	2.4
No teaching and no DSH	333	3.1	-0.2	0.1	-0.6	-0.2	0.2	2.5
Special Hospital Types:								
RRC	471	3.1	0.1	0.1	1.1	-0.1	0.1	2.5
SCH	304	2.6	-0.2	0	0	-0.1	0.1	2.4
MDH	146	2.8	-0.4	0.2	0.3	-0.1	0.1	2.2
SCH and RRC	148	2.7	-0.2	-0.1	0.5	-0.1	0	2.4
MDH and RRC	24	2.8	-0.3	0.1	0.5	-0.1	0	2.3
Type of Ownership:								
Voluntary	1,884	3.1	0	0	0	0	0.1	2.5
Proprietary	826	3.1	-0.1	-0.1	0	0	0.1	2.6
Government	488	3	0.1	0.1	-0.2	0	0	2.5
Medicare Utilization as a Percent of Inpatient Days:								
0-25	601	3.1	0.1	0.1	-0.3	-0.1	0	2.7
25-50	2,108	3.1	0	0	0	0	0.1	2.5
50-65	391	3	-0.2	0	0.4	0.1	0.2	2.1
Over 65	64	2.8	-1.2	-0.4	-0.5	0.4	0	1.5
FY 2021 Reclassifications by the Medicare Geographic Classification Review Board:								
All Reclassified Hospitals	949	3	0	0.1	1.3	-0.1	0.1	2.6
Non-Reclassified Hospitals	2,250	3.1	0	-0.1	-0.9	0	0.1	2.5
Urban Hospitals Reclassified	778	3.1	0	0.1	1	-0.1	0.1	2.5

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2021 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Proposed FY 2021 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2021 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Proposed Frontier State Wage Index and Proposed Outmigration Adjustment (6)[7]	All Proposed FY 2021 Changes (7)[8]
Urban Non-Reclassified Hospitals	1,693	3.1	0	-0.1	-0.9	0.1	0.1	2.6
Rural Hospitals Reclassified Full Year	310	2.8	-0.2	0	1.9	-0.1	0.1	2.3
Rural Non-Reclassified Hospitals Full Year	418	2.8	-0.3	0	-0.3	-0.2	0.2	2.2
All Section 401 Reclassified Hospitals	485	3	0.1	0	0.8	-0.1	0.1	2.5
Other Reclassified Hospitals (Section 1886(d)(8)(B))	54	3	-0.3	0.1	1.7	0.4	0	2.2

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2019, and hospital cost report data are from reporting periods beginning in FY 2017 and FY 2016.

[2] This column displays the payment impact of the proposed hospital rate update and other adjustments, including the proposed 2.6 percent update to the national standardized amount and the proposed hospital-specific rate (the estimated 3.0 percent market basket update reduced by 0.4 percentage point for the proposed multifactor productivity adjustment), and the proposed 0.5 percentage point adjustment to the national standardized amount required under section 414 of the MACRA.

[3] This column displays the payment impact of the proposed changes to the Version 38 GROUPER, the proposed changes to the relative weights and the recalibration of the MS-DRG weights based on FY 2019 MedPAR data in accordance with section 1886(d)(4)(C)(iii) of the Act. This column displays the application of the proposed recalibration budget neutrality factor of 0.998761 in accordance with section 1886(d)(4)(C)(iii) of the Act.

[4] This column displays the payment impact of the proposed update to wage index data using FY 2017 cost report data and the OMB labor market area delineations based on 2010 Decennial Census data. This column displays the payment impact of the application of the proposed wage budget neutrality factor, which is calculated separately from the recalibration budget neutrality factor, and is calculated in accordance with section 1886(d)(3)(E)(i) of the Act. The proposed wage budget neutrality factor is 0.999362.

[5] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2021 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2021. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the proposed geographic budget neutrality factor of 0.988003.

[6] This column displays the effects of the proposed rural floor. The Affordable Care Act requires the rural floor budget neutrality adjustment to be a 100 percent national level adjustment. The proposed rural floor budget neutrality factor applied to the wage index is 0.993991.

[7] This column shows the combined impact of the policy required under section 10324 of the Affordable Care Act that hospitals located in frontier States have a wage index no less than 1.0 and of section 1886(d)(13) of the Act, as added by section 505 of Pub. L. 108-173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. These are not budget neutral policies.

[8] This column shows the estimated change in payments from FY 2020 to FY 2021 including an estimated decrease in outlier payments of 0.4 percent (from our current estimate of FY 2020 outlier payments of approximately 5.5 percent to 5.1 percent projected for FY 2021 based on the FY 2019 MedPAR data used for this proposed rule calculated for purposes of this impact analysis). This column also includes the effects of the proposed adoption of the revised labor market area delineations in OMB Bulletin 18-04 and the effects of the proposed transition to apply a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index from the prior fiscal year.

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a. Effects of the Proposed Hospital Update and Other Proposed Adjustments (Column 1)

As discussed in section IV.B. of the preamble of this proposed rule, this column includes the proposed hospital update, including the proposed 3.0 percent market basket update and the proposed reduction of 0.4 percentage point for the multifactor

productivity adjustment. In addition, as discussed in section II.D. of the preamble of this proposed rule, this column includes the FY 2021 +0.5 percentage point adjustment required under section 414 of the MACRA. As a result, we are proposing to make a 3.1 percent update to the national standardized amount. This column also includes the proposed update to the hospital-specific rates which includes the proposed 3.0 percent market basket update and the proposed reduction of 0.4 percentage point for the multifactor productivity adjustment. As a result, we are proposing to make a 2.6 percent update to the hospital-specific rates.

Overall, hospitals would experience a 3.1 percent increase in payments primarily due to the combined effects of the proposed hospital update to the national standardized amount and the proposed hospital update to the hospital-specific rate. Hospitals that are paid under the hospital-specific rate would experience a 2.6 percent increase in payments; therefore, hospital categories containing hospitals paid under the hospital-specific rate would experience a lower than average increase in payments.

b. Effects of the Proposed Changes to the MS–DRG Reclassifications and Relative Cost-Based Weights With Recalibration Budget Neutrality (Column 2)

Column 2 shows the effects of the proposed changes to the MS–DRGs and relative weights with the application of the proposed recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Consistent with section 1886(d)(4)(C)(iii) of the Act, we calculated a proposed recalibration budget neutrality factor to account for the changes in MS–DRGs and relative weights to ensure that the overall payment impact is budget neutral.

As discussed in section II.E. of the preamble of this proposed rule, the FY 2021 MS–DRG relative weights will be 100 percent cost-based and 100 percent MS–DRGs. For FY 2021, the MS–DRGs are calculated using the FY 2019 MedPAR data grouped to the proposed Version 38 (FY 2021) MS–DRGs. The methodology to calculate the proposed relative weights and the reclassification changes to the GROUPER are described in more detail in section II.G. of the preamble of this proposed rule.

The ''All Hospitals'' line in Column 2 indicates that proposed changes due to the MS–DRGs and relative weights would result in a 0.0 percent change in payments with the application of the proposed recalibration budget neutrality factor of 0.998761to the standardized amount. Hospital categories that generally treat relatively less complex cases, such as rural hospitals and smaller urban hospitals, would experience a decrease in their payments, while hospitals that generally treat relatively more complex cases, such as larger urban hospitals, would experience an increase in their payments under the proposed relative weights. For example, rural hospitals with 50–99 beds and urban hospitals of 99 beds or less would experience a −0.3 percent decrease in payments. Conversely, urban hospitals of 500 beds or more would experience a +0.2 percent increase in payments.

c. Effects of the Proposed Wage Index Changes (Column 3)

Column 3 shows the impact of the proposed updated wage data using FY 2017 cost report data, with the application of the proposed wage budget neutrality factor. The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on the Core Based Statistical Areas (CBSAs) established by OMB. The current statistical standards used in FY 2021 are based on OMB standards published on February 28, 2013 (75 FR 37246 and 37252), and 2010 Decennial Census data (OMB Bulletin No. 13–01), as updated in OMB Bulletin Nos. 15–01 and 17–01. (We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963) for a full discussion on our adoption of the OMB labor market area delineations, based on the 2010 Decennial Census data, effective beginning with the FY 2015 IPPS wage index, to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913) for a discussion of our adoption of the CBSA updates in OMB Bulletin No. 15–01, which were effective beginning with the FY 2017 wage index, and to the FY 2020 IPPS/LTCH PPS final rule (83 FR 41362) for a discussion of our adoption of the CBSA update in OMB Bulletin No. 17–01 for the FY 2020 wage index.)

As discussed in section III.A.2.a. of the preamble of this proposed rule, OMB Bulletin No. 18–04 established revised delineations for statistical areas, and in order to implement these changes for the IPPS, it is necessary to identify the new labor market area delineation for each county and hospital in the country that would be affected by the revised OMB delineations. We believe that adopting the revised OMB delineations described in OMB Bulletin No. 18–04 would allow us to maintain a more accurate payment system that reflects the reality of population shifts and labor market conditions. We further believe that using these delineations will increase the integrity of the IPPS wage index system by creating a more accurate representation of geographic variations in wage levels. As discussed in this section, in this proposed rule, we are proposing to implement the revised OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, effective beginning with the FY 2021 IPPS wage index.

Section 1886(d)(3)(E) of the Act requires that, beginning October 1, 1993, we annually update the wage data used to calculate the wage index. In accordance with this requirement, the proposed wage index for acute care hospitals for FY 2021 is based on data submitted for hospital cost reporting periods, beginning on or after October 1, 2016 and before October 1, 2017. The estimated impact of the updated wage data using the FY 2017 cost report data and the proposed revised OMB labor market area delineations on hospital payments is isolated in Column 3 by holding the other proposed payment parameters constant in this simulation. That is, Column 3 shows the proposed percentage change in payments when going from a model using the FY 2020 wage index, based on FY 2016 wage data, the labor-related share of 68.3 percent, under the proposed revised OMB delineations and having a 100-percent occupational mix adjustment applied, to a model using the proposed FY 2021 pre-reclassification wage index based on FY 2017 wage data with the labor-related share of 68.3 percent, under the proposed revised OMB delineations, also having a 100-percent occupational mix adjustment applied, while holding other payment parameters, such as use of the proposed Version 38 MS–DRG GROUPER constant. The proposed FY 2021 occupational mix adjustment is based on the CY 2016 occupational mix survey.

In addition, the column shows the impact of the application of the proposed wage budget neutrality to the national standardized amount. In FY 2010, we began calculating separate wage budget neutrality and recalibration budget neutrality factors, in accordance with section 1886(d)(3)(E) of the Act, which specifies that budget neutrality to account for wage index changes or updates made under that subparagraph must be made without regard to the 62 percent labor-related share guaranteed under section 1886(d)(3)(E)(ii) of the Act. Therefore, for FY 2021, we are proposing to calculate the proposed wage budget neutrality factor to ensure that payments under updated wage data and the labor-related share of 68.3 percent are budget neutral, without regard to the lower labor-related share of 62 percent applied to hospitals with a wage index less than or equal to 1.0. In other words, the wage budget neutrality is calculated under the assumption that all hospitals receive the higher labor-related share of the standardized amount. The proposed FY 2021 wage budget neutrality factor is 0.999362 and the overall proposed payment change is 0 percent.

Column 3 shows the impacts of updating the wage data using FY 2017 cost reports. Overall, the new wage data and the labor-related share, combined with the proposed wage budget neutrality adjustment, would lead to no change for all hospitals, as shown in Column 3.

In looking at the wage data itself, the national average hourly wage would increase 1.02 percent compared to FY 2020. Therefore, the only manner in which to maintain or exceed the previous year's wage index was to match or exceed the proposed 1.02 percent increase in the national average hourly wage. Of the 3,181 hospitals with wage data for both FYs 2020 and 2021, 1,655 or 52 percent would experience an average hourly wage increase of 1.02 percent or more.

The following chart compares the shifts in wage index values for hospitals due to proposed changes in the average hourly wage data for FY 2021 relative to FY 2020. These figures reflect proposed changes in the ''pre-reclassified, occupational mix-adjusted wage index,'' that is, the wage index before the application of geographic reclassification, the rural floor, the out-migration adjustment, and other wage index exceptions and adjustments. We note that this analysis was

performed by applying the proposed revised OMB labor market area delineations to the FY 2021 proposed wage data and also by recomputing the FY 2020 final wage data to reflect the proposed revised OMB delineations. (We refer readers to sections III.G. through III.L. of the preamble of this proposed rule for a complete discussion of the exceptions and adjustments to the wage index.) We note that the ''post-reclassified wage index'' or ''payment wage index,'' which is the wage index that includes all such exceptions and adjustments (as reflected in Tables 2 and 3 associated with this proposed rule, which are available via the internet on the CMS website) is used to adjust the labor-related share of a hospital's standardized amount, either 68.3 percent or 62 percent, depending upon whether a hospital's wage index is greater than 1.0 or less than or equal to 1.0. Therefore, the proposed pre-reclassified wage index figures in the following chart may illustrate a somewhat larger or smaller proposed change than would occur in a hospital's payment wage index and total payment.

The following chart shows the projected impact of proposed changes in the area wage index values for urban and rural hospitals.

Proposed FY 2021 Percentage Change in Area Wage Index Values	Number of Hospitals	
	Urban	Rural
Increase 10 percent or more	7	2
Increase greater than or equal to 5 percent and less than 10 percent	41	0
Increase or decrease less than 5 percent	2,331	722
Decrease greater than or equal to 5 percent and less than 10 percent	87	0
Decrease 10 percent or more	25	5
Unchanged	2	0

d. Effects of MGCRB Reclassifications (Column 4)

Our impact analysis to this point has assumed acute care hospitals are paid on the basis of their actual geographic location (with the exception of ongoing policies that provide that certain hospitals receive payments on bases other than where they are geographically located). The proposed changes in Column 4 reflect the per case payment impact of moving from this baseline to a simulation incorporating the MGCRB decisions for FY 2021.

By spring of each year, the MGCRB makes reclassification determinations that will be effective for the next fiscal year, which begins on October 1. The MGCRB may approve a hospital's reclassification request for the purpose of using another area's wage index value. Hospitals may appeal denials of MGCRB decisions to the CMS Administrator. Further, hospitals have 45 days from the date the IPPS proposed rule is issued in the **Federal Register** to decide whether to withdraw or terminate an approved geographic reclassification for the following year (we refer readers to the discussion of our clarification of this policy in section III.I.2. of the preamble to this proposed rule).

The overall effect of geographic reclassification is required by section 1886(d)(8)(D) of the Act to be budget neutral. Therefore, for purposes of this impact analysis, we are proposing to apply an adjustment of 0.988003 to ensure that the effects of the reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are budget neutral (section II.A. of the Addendum to this proposed rule). Geographic reclassification generally benefits hospitals in rural areas. We estimate that the geographic reclassification would increase payments to rural hospitals by an average of 1.1 percent. By region, most rural hospital categories would experience increases in payments due to MGCRB reclassifications. Hospitals in the rural West North Central and Mountain regions would experience a decrease in payments due to MGCRB reclassifications, while hospitals in the rural New England region would experience no change in payments due to MGCRB reclassifications,

Table 2 listed in section VI. of the Addendum to this proposed rule and available via the internet on the CMS website reflects the reclassifications for FY 2021.

e. Effects of the Proposed Rural Floor, Including Application of National Budget Neutrality (Column 5)

As discussed in section III.B. of the preamble of the FY 2009 IPPS final rule, the FY 2010 IPPS/RY 2010 LTCH PPS final rule, the FYs 2011 through 2020 IPPS/LTCH PPS final rules, and this FY 2021 IPPS/LTCH PPS proposed rule, section 4410 of Public Law 105–33 established the rural floor by requiring that the wage index for a hospital in any urban area cannot be less than the wage index applicable to hospitals located in rural areas in the same State. We will apply a uniform budget neutrality adjustment to the wage index. Column 5 shows the effects of the proposed rural floor.

The Affordable Care Act requires that we apply one rural floor budget neutrality factor to the wage index nationally. We have calculated a proposed FY 2021 rural floor budget neutrality factor to be applied to the wage index of 0.993991, which would reduce wage indexes by 0.6 percent.

Column 5 shows the projected impact of the proposed rural floor with the national rural floor budget neutrality factor applied to the wage index based on the proposed revised OMB labor market area delineations. The column compares the post-reclassification FY 2021 wage index of providers before the rural floor adjustment and the post-reclassification FY 2021 wage index of providers with the rural floor adjustment based on the proposed revised OMB labor market area delineations. Only urban hospitals can benefit from the rural floor. Because the provision is budget neutral, all other hospitals that do not receive an increase to their wage index from the rural floor adjustment (that is, all rural hospitals and those urban hospitals to which the adjustment is not made) would experience a decrease in payments due to the budget neutrality adjustment that is applied to the wage index nationally. (As finalized in the FY 2020 IPPS/LTCH PPS final rule, we calculate the rural floor without including the wage data of hospitals that have reclassified as rural under § 412.103.)

We estimate that 255 hospitals would receive the rural floor in FY 2021. All IPPS hospitals in our model would have their wage indexes reduced by the proposed rural floor budget neutrality adjustment of 0.993991 We project that, in aggregate, rural hospitals would experience a 0.1 percent decrease in payments as a result of the application of the proposed rural floor budget neutrality because the rural hospitals do not benefit from the rural floor, but have their wage indexes downwardly adjusted to ensure that the application of the rural floor is budget neutral overall. We project that, in the aggregate, hospitals located in urban areas would experience no change in payments because increases in payments to hospitals benefitting from the rural floor offset decreases in payments to nonrural floor urban hospitals whose wage index is downwardly adjusted by the rural floor budget neutrality factor. Urban hospitals in the New England region would experience a 2.1 percent increase in payments primarily due to the application of the rural floor in Massachusetts. Fifty-three urban providers in Massachusetts are expected to receive the rural floor wage index value, including the rural floor budget neutrality adjustment, which would increase payments overall to hospitals in Massachusetts by an estimated $145 million. We estimate that Massachusetts hospitals would receive approximately a 3.8 percent increase in IPPS payments due to the application of the rural floor in FY 2021. Urban Puerto Rico hospitals are expected to experience a 0.2 percent increase in payments as a result of the application of the proposed rural floor for FY 2021.

f. Effects of the Application of the Proposed Frontier State Wage Index and Proposed Out-Migration Adjustment (Column 6)

This column shows the combined effects of the application of section 10324(a) of the Affordable Care Act, which requires that we establish a minimum post-reclassified wage index of 1.00 for all hospitals located in ''frontier States,'' and the effects of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. These two wage index provisions are not budget neutral and would increase payments overall by 0.1 percent compared to the provisions not being in effect.

The term ''frontier States'' is defined in the statute as States in which at least 50 percent of counties have a population density less than 6 persons per square mile. Based on these criteria, 5 States (Montana, Nevada, North Dakota, South Dakota, and Wyoming) are considered frontier States and 45 hospitals located in those States would receive a frontier wage index of 1.0000. Overall, this provision is not budget neutral and is estimated to increase IPPS operating payments by approximately $70 million. Urban hospitals located in the West North Central region would experience an increase in payments by 0.6 percent, because many of the hospitals located in this region are frontier State hospitals.

In addition, section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index. Hospitals located in counties that qualify for the payment adjustment will receive an increase in the wage index that is equal to a weighted average of the difference between the wage index of the resident county, post-reclassification and the higher wage index work area(s), weighted by the overall percentage of workers who are employed in an area with a higher wage index. There are an estimated 203 providers that would receive the out-migration wage adjustment in FY 2021. Rural hospitals generally would qualify for the adjustment, resulting in a 0.1 percent increase in payments. This provision appears to benefit section 401 hospitals and RRCs in that they would each experience a 0.1 percent increase in payments. This out-migration wage adjustment also is not budget neutral, and we estimate the impact of these providers receiving the out-migration increase would be approximately $46 million.

g. Effects of All FY 2021 Proposed Changes (Column 7)

Column 7 shows our estimate of the proposed changes in payments per discharge from FY 2020 and FY 2021, resulting from all proposed changes reflected in this proposed rule for FY 2021. It includes combined effects of the year-to-year change of the previous columns in the table.

The proposed average increase in payments under the IPPS for all hospitals is approximately 2.5 percent for FY 2021 relative to FY 2020 and for this row is primarily driven by the proposed changes reflected in Column 1. Column 7 includes the proposed annual hospital update of 3.1 percent to the national standardized amount. This proposed annual hospital update includes the proposed 3.0 percent market basket update and the proposed 0.4 percentage point reduction for the multifactor productivity adjustment. As discussed in section II.D. of the preamble of this proposed rule, this column also includes the +0.5 percentage point adjustment required under section 414 of the MACRA. Hospitals paid under the hospital-specific rate would receive a 2.6 percent hospital update. As described in Column 1, the proposed annual hospital update with the proposed +0.5 percent adjustment for hospitals paid under the national standardized amount, combined with the proposed annual hospital update for hospitals paid under the hospital-specific rates, would result in a 2.5 percent increase in payments in FY 2021 relative to FY 2020. This estimated increase also reflects the effects of the proposed adoption of the revised labor market area delineations in OMB Bulletin 18–04 and the effects of the proposed transition to apply a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index from the prior fiscal year. Additionally, the estimated increase also reflects an estimated decrease in outlier payments of 0.4 percent (from our current estimate of FY 2020 outlier payments of approximately 5.5 percent to 5.1 percent projected for FY 2021 based on the FY 2019 MedPAR data used for this proposed rule calculated for purposes of this impact analysis). There are also interactive effects among the various factors comprising the payment system that we are not able to isolate, which contribute to our estimate of the proposed changes in payments per discharge from FY 2020 and FY 2021 in Column 7.

Overall payments to hospitals paid under the IPPS due to the proposed applicable percentage increase and proposed changes to policies related to MS–DRGs, geographic adjustments, and outliers are estimated to increase by 2.5 percent for FY 2021. Hospitals in urban areas would experience a 2.5 percent increase in payments per discharge in FY 2021 compared to FY 2020. Hospital payments per discharge in rural areas are estimated to increase by 2.3 percent in FY 2021.

3. Impact Analysis of Table II

Table II presents the projected impact of the proposed changes for FY 2021 for urban and rural hospitals and for the different categories of hospitals shown in Table I. It compares the estimated average payments per discharge for FY 2020 with the estimated proposed average payments per discharge for FY 2021, as calculated under our models. Therefore, this table presents, in terms of the average dollar amounts paid per discharge, the combined effects of the proposed changes presented in Table I. The estimated percentage changes shown in the last column of Table II equal the estimated percentage changes in average payments per discharge from Column 7 of Table I.

TABLE II.--IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2021 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM (PAYMENTS PER DISCHARGE)

	Number of Hospitals (1)	Estimated Average FY 2020 Payment Per Discharge (2)	Estimated Proposed Average FY 2021 Payment Per Discharge (3)	Proposed FY 2021 Changes (4)
All Hospitals	3,199	13,484	13,824	2.5
By Geographic Location:				
Urban hospitals	2,459	13,859	14,211	2.5
Rural hospitals	740	10,005	10,234	2.3
Bed Size (Urban):				
0-99 beds	634	10,939	11,180	2.2
100-199 beds	752	11,335	11,619	2.5
200-299 beds	438	12,604	12,908	2.4
300-499 beds	414	13,904	14,256	2.5
500 or more beds	221	17,172	17,630	2.7
Bed Size (Rural):				
0-49 beds	300	8,772	8,951	2
50-99 beds	259	9,546	9,761	2.3
100-149 beds	98	9,823	10,048	2.3
150-199 beds	44	10,386	10,633	2.4
200 or more beds	39	11,578	11,855	2.4
Urban by Region:				
New England	112	14,840	15,192	2.4
Middle Atlantic	305	15,679	16,103	2.7
South Atlantic	402	12,310	12,632	2.6
East North Central	380	12,992	13,313	2.5
East South Central	144	11,744	12,043	2.5
West North Central	159	13,362	13,658	2.2
West South Central	364	12,962	13,301	2.6
Mountain	172	14,052	14,331	2
Pacific	371	17,327	17,797	2.7
Puerto Rico	50	11,903	12,126	1.9
Rural by Region:				
New England	19	13,885	14,217	2.4
Middle Atlantic	50	9,695	9,933	2.5
South Atlantic	115	9,404	9,606	2.1
East North Central	114	10,255	10,496	2.4
East South Central	144	8,964	9,179	2.4
West North Central	89	10,452	10,675	2.1
West South Central	136	8,761	8,962	2.3
Mountain	49	11,998	12,249	2.1
Pacific	24	13,459	13,766	2.3
By Payment Classification:				
Urban hospitals	2,028	13,563	13,912	2.6
Rural areas	1,171	13,341	13,665	2.4
Teaching Status:				
Nonteaching	2,043	10,966	11,222	2.3
Fewer than 100 residents	901	12,695	13,015	2.5
100 or more residents	255	19,718	20,253	2.7

	Number of Hospitals (1)	Estimated Average FY 2020 Payment Per Discharge (2)	Estimated Proposed Average FY 2021 Payment Per Discharge (3)	Proposed FY 2021 Changes (4)
Urban DSH:				
Non-DSH	505	11,421	11,685	2.3
100 or more beds	1,273	14,041	14,406	2.6
Less than 100 beds	352	10,323	10,545	2.2
Rural DSH:				
SCH	257	11,063	11,317	2.3
RRC	538	13,999	14,351	2.5
100 or more beds	59	13,045	13,296	1.9
Less than 100 beds	215	8,310	8,490	2.2
Urban teaching and DSH:				
Both teaching and DSH	738	15,243	15,647	2.6
Teaching and no DSH	70	12,427	12,706	2.2
No teaching and DSH	887	11,349	11,626	2.4
No teaching and no DSH	333	10,681	10,947	2.5
Special Hospital Types:				
RRC	471	14,095	14,451	2.5
SCH	304	11,877	12,158	2.4
MDH	146	8,960	9,159	2.2
SCH and RRC	148	12,223	12,513	2.4
MDH and RRC	24	10,361	10,597	2.3
Type of Ownership:				
Voluntary	1,884	13,516	13,856	2.5
Proprietary	826	11,833	12,137	2.6
Government	488	15,531	15,918	2.5
Medicare Utilization as a Percent of Inpatient Days:				
0-25	601	16,734	17,181	2.7
25-50	2,108	13,207	13,540	2.5
50-65	391	10,552	10,777	2.1
Over 65	64	8,587	8,719	1.5
FY 2021 Reclassifications by the Medicare Geographic Classification Review Board:				
All Reclassified Hospitals	949	13,781	14,138	2.6
Non-Reclassified Hospitals	2,250	13,288	13,616	2.5
Urban Hospitals Reclassified	778	14,195	14,549	2.5
Urban Nonreclassified Hospitals	1,693	13,606	13,955	2.6
Rural Hospitals Reclassified Full Year	310	10,162	10,400	2.3
Rural Nonreclassified Hospitals Full Year	418	9,774	9,987	2.2
All Section 401 Reclassified Hospitals:	485	14,471	14,827	2.5
Other Reclassified Hospitals (Section 1886(d)(8)(B))	54	9,436	9,641	2.2

H. Effects of Other Proposed Policy Changes

In addition to those proposed policy changes discussed previously that we are able to model using our IPPS payment simulation model, we are proposing to make various other changes in this proposed rule. As noted in section I.G. of this regulatory impact analysis, our payment simulation model uses the most recent available claims data to estimate the impacts on payments per case of certain proposed changes in this proposed rule. Generally, we have limited or no specific data available with which to estimate the impacts of these proposed changes using that payment simulation model. For those proposed changes, we have attempted to predict the payment impacts based upon our experience and other more limited data. Our estimates of the likely impacts associated with these other proposed changes are discussed in this section.

1. Effects of Proposed Policies Relating to New Medical Service and Technology Add-On Payments

a. Proposed Changes to the Alternative Pathway for Certain Antimicrobial Products

In section II.H.9.b of the preamble of this proposed rule, we are proposing to revise § 412.87(d)(1) to add drugs approved under FDA's LPAD pathway to the current alternative new technology add-on payment pathway for QIDPs, beginning with

discharges occurring on or after October 1, 2021.

Given the relatively recent introduction of the FDA's LPAD pathway there have not been any drugs that were approved under the FDA's LPAD pathway that applied for an NTAP under the IPPS and were not approved for that NTAP. If all of the future LPADs that would have applied for new technology add-on payments would have been approved under existing criteria, this proposal has no impact relative to current policy. To the extent that there are future LPADs that are the subject of applications for new technology add-on payments, and those applications would have been denied under the current new technology add-on payment criteria, this proposal is a cost, but that cost is not estimable. We also note that as this proposal, if finalized, would be effective beginning with new technology add-on payment applications for FY 2022, there would be no impact of this proposal in FY 2021.

b. Proposed Change to Announcement of Determinations and Deadline for Consideration of New Medical Service or Technology Applications for Certain Antimicrobial Products

In section II.H.9.c. of the preamble of this proposed rule, we are proposing to revise § 412.87(e) to add a new paragraph (3) which would provide for conditional new technology add-on payment approval for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products at § 412.87(d) that does not receive FDA marketing authorization by the July 1 deadline specified in § 412.87(e)(2), provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments.

If all of the future antimicrobial products eligible for the alternative pathway for certain antimicrobial products at § 412.87(d) receive marketing authorization by the July 1 deadline specified in § 412.87(e)(2), this proposal has no impact. To the extent that there are future antimicrobial products that do not receive marketing authorization by that deadline, but do receive FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments, this proposal is a cost, but that cost is not estimable.

c. Proposed FY 2021 Status of Technologies Approved for FY 2020 New Technology Add-On Payments

In section II.H.4. of the preamble of this proposed rule, we are proposing to discontinue new technology add-on payments for the AQUABEAM System (Aquablation), ERLEADA®, GIAPREZA™, the remede-® System, VABOMERE™, VYXEOS™, the Sentinel® Cerebral Protection System, and KYMRIAH® and YESCARTA® for FY 2021 because these technologies will have been on the U.S. market for 3 years. We also are proposing to continue to make new technology add-on payments for AndexXa™, AZEDRA®, BALVERSA™, Cablivi®, ELZONRIS®, Esketamine, Jakafi®, T2 Bacteria Test Panel, XOSPATA®, and ZEMDRI™ in FY 2021 because these technologies would still be considered new for purposes of new technology add-on payments. Under § 412.88(a)(2) and in conjunction with our proposed change to the calculation of the new technology add-on payments for products approved under the LPAD pathway, the new technology add-on payment for each case would be limited to the lesser of: (1) 65 percent of the costs of the new technology (or 75 percent of the costs for technologies designated as QIDPs or approved under the LPAD pathway); or (2) 65 percent of the amount by which the costs of the case exceed the standard MS–DRG payment for the case (or 75 percent of the amount for technologies designated as QIDPs or approved under the LPAD pathway). Because it is difficult to predict the actual new technology add-on payment for each case, our estimates below are based on the increase in new technology add-on payments for FY 2021 as if every claim that would qualify for a new technology add-on payment would receive the maximum add-on payment. The following are estimates for FY 2021 for the 10 technologies for which we are proposing to continue to make new technology add-on payments in FY 2021:

- Based on the applicant's estimate for FY 2019, we currently estimate that new technology add-on payments for AndexXa™ would increase overall FY 2021 payments by $98,755,313 (maximum add-on payment of $18,281.25 * 5,402 patients).
- Based on the applicant's estimate for FY 2020, we currently estimate that new technology add-on payments for AZEDRA® would increase overall FY 2021 payments by $39,260,000 (maximum add-on payment of $98,150 * 400 patients).
- Based on the applicant's estimate for FY 2020, we currently estimate that new technology add-on payments for BALVERSA™ would increase overall FY 2021 payments by $178,162 (maximum add-on payment of $3,563.23 * 50 patients).
- Based on the applicant's estimate for FY 2020, we currently estimate that new technology add-on payments for Cablivi® would increase overall FY 2021 payments by $4,351,165 (maximum add-on payment of $33,215 * 131 patients).
- Based on the applicant's estimate for FY 2020, we currently estimate that new technology add-on payments for ELZONRIS® would increase overall FY 2021 payments by $30,985,668 (maximum add-on payment of $125,448.05 * 247 patients).
- Based on the applicant's estimate for FY 2020, we currently estimate that new technology add-on payments for Esketamine would increase overall FY 2021 payments by $6,494,656 (maximum add-on payment of $1,014.79 * 6,400 patients).
- Based on the applicant's estimate for FY 2020, we currently estimate that new technology add-on payments for Jakafi® would increase overall FY 2021 payments by $556,788 (maximum add-on payment of $3,977.06 * 140 patients).
- Based on the applicant's estimate for FY 2020, we currently estimate that new technology add-on payments for T2 Bacteria Test Panel would increase overall FY 2021 payments by $3,669,803 (maximum add-on payment of $97.50 * 37,639 patients).
- Based on the applicant's estimate for FY 2020, we currently estimate that new technology add-on payments for XOSPATA® would increase overall FY 2021 payments by $13,710,938 (maximum add-on payment of $7,312.50 * 1,875 patients).
- Based on the applicant's estimate for FY 2019 we currently estimate that new technology add-on payments for ZEMDRI™ would increase overall FY 2021 payments by $10,209,375 (maximum add-on payment of $4,083.75 * 2,500 patients).

Overall, we estimate that FY 2021 new technology add-on payments for technologies that were approved in FY 2020 would be approximately $208 million.

d. Proposed FY 2021 Applications for New Technology Add-On Payments

In sections II.G.5. and 6. of the preamble to this proposed rule, we discuss 24 technologies for which we received applications for add-on payments for new medical services and technologies for FY 2021. We note that three applicants withdrew their application prior to the issuance of this proposed rule. As explained in the preamble to this proposed rule, add-on payments for new medical services and technologies under section 1886(d)(5)(K) of the Act are not required to be budget neutral. As discussed in section II.G.6. of the preamble of this proposed rule, under the alternative pathway for new technology add-on payments, new technologies that are medical products with a QIDP designation or are part of the Breakthrough Device program will be considered new and not substantially similar to an existing technology and will not need to demonstrate that the technology represents a substantial clinical improvement. These technologies must still meet the cost criterion.

As also discussed in section II.G.6. of the preamble of this proposed rule, to provide additional transparency and predictability with respect to these technologies, in this proposed rule we are making a proposal to approve or disapprove each of the nine alternative pathway applications based on whether the technology meets the cost criterion. Specifically, we are proposing to approve the nine alternative pathway applicant technologies (3 Breakthrough devices and 6 QIDPs) for FY 2021 based on our analysis of the cost criterion. Based on preliminary information from the applicants at the time of this proposed rule, we estimate that total payments for the nine technologies that applied under the alternative pathway, if approved, would be approximately $240 million for FY 2021. Total estimated FY 2021 payments for new technologies that are designated as a QIDP would be approximately $200 million, and total estimated FY 2021 payments for new technologies that are part of the Breakthrough Device program would be approximately $40 million. We note that these estimated payments may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We have not yet determined whether any of the 15 technologies that applied under the traditional pathway discussed in section

II.G.5. of the preamble of this proposed rule will meet the criteria for new technology add-on payments for FY 2021. Consequently, it is premature to estimate the potential payment impact of these 15 technologies for any potential new technology add-on payments for FY 2021. We note that, as in past years, if any of the 15 technologies that applied under the traditional pathway are found to be eligible for new technology add-on payments for FY 2021, in the FY 2021 IPPS/LTCH PPS final rule, we would discuss the estimated payment impact for FY 2021.

2. Effects of Proposed Changes to MS–DRGs Subject to the Postacute Care Transfer Policy and the MS–DRG Special Payment Policy

In section IV.A. of the preamble of this proposed rule, we discuss our proposed changes to the list of MS–DRGs subject to the postacute care transfer policy and the MS DRG special payment policy for FY 2021. As reflected in Table 5 listed in section VI. of the Addendum to this proposed rule (which is available via the internet on the CMS website), using criteria set forth in regulations at 42 CFR 412.4, we evaluated MS–DRG charge, discharge, and transfer data to determine which proposed new or revised MS–DRGs would qualify for the postacute care transfer and MS–DRG special payment policies. As a result of our proposals to revise the MS–DRG classifications for FY 2021, which are discussed in section II.F. of the preamble of this proposed rule, we are proposing to add two MS–DRGs to the list of MS–DRGs that would be subject to the postacute care transfer policy and the MS–DRG special payment policy. Column 2 of Table I in this Appendix A shows the effects of the proposed changes to the MS–DRGs and the proposed relative payment weights and the application of the proposed recalibration budget neutrality factor to the standardized amounts.

Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate DRG classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. The analysis and methods for determining the changes due to the MS–DRGs and relative payment weights account for and include changes as a result of the proposed changes to the MS–DRGs subject to the MS–DRG postacute care transfer and MS–DRG special payment policies. We refer readers to section I.G. of this Appendix A for a detailed discussion of payment impacts due to the proposed MS–DRG reclassification policies for FY 2021.

3. Effects of the Proposed Changes to Medicare DSH and Uncompensated Care Payments for FY 2021

As discussed in section IV.G. of the preamble of this proposed rule, under section 3133 of the Affordable Care Act, hospitals that are eligible to receive Medicare DSH payments will receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments under section 1886(d)(5)(F) of the Act. The remainder, equal to an estimate of 75 percent of what formerly would have been paid as Medicare DSH payments (Factor 1), reduced to reflect changes in the percentage of uninsured individuals and any additional statutory adjustment (Factor 2), is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. Each hospital eligible for Medicare DSH payments will receive an additional payment based on its estimated share of the total amount of uncompensated care for all hospitals eligible for Medicare DSH payments. The uncompensated care payment methodology has redistributive effects based on the proportion of a hospital's amount of uncompensated care relative to the aggregate amount of uncompensated care of all hospitals eligible for Medicare DSH payments (Factor 3). The change to Medicare DSH payments under section 3133 of the Affordable Care Act is not budget neutral.

In this proposed rule, we are proposing to establish the amount to be distributed as uncompensated care payments to DSH eligible hospitals, which for FY 2021 is $7,816,726,242.92. This figure represents 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a proposed Factor 2 of 67.86 percent. For FY 2020, the amount available to be distributed for uncompensated care was $8,350,599,096.04, or 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 67.14 percent. To calculate Factor 3 for FY 2021, we are proposing to use information on uncompensated care costs from Worksheet S–10 of hospitals' FY 2017 cost reports for all eligible hospitals, with the exception of Puerto Rico hospitals and Indian Health Service and Tribal hospitals, for which we are proposing to continue to use low-income insured days from FY 2013 cost report and FY 2018 SSI days to determine Factor 3. For purposes of this proposed rule, we used uncompensated care data from the HCRIS database, as updated through February 19, 2020, Medicaid days from hospitals' FY 2013 cost reports from the same extract of HCRIS, and SSI days from the FY 2018 SSI ratios. For a complete discussion of the proposed methodology for calculating Factor 3, we refer readers to section IV.G.4. of the preamble of this proposed rule.

To estimate the impact of the combined effect of the proposed changes to Factors 1 and 2, as well as the proposed changes to the data used in determining Factor 3, on the calculation of Medicare uncompensated care payments, we compared total uncompensated care payments estimated in the FY 2020 IPPS/LTCH PPS final rule to total uncompensated care payments estimated in this FY 2021 IPPS/LTCH PPS proposed rule. For FY 2020, we calculated 75 percent of the estimated amount that would be paid as Medicare DSH payments absent section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 67.14 percent and multiplied by a Factor 3 calculated using the methodology described in the FY 2020 IPPS/LTCH PPS final rule. For FY 2021, we calculated 75 percent of the estimated amount that would be paid as Medicare DSH payments absent section 3133 of the Affordable Care Act, adjusted by a proposed Factor 2 of 67.86 percent and multiplied by a Factor 3 calculated using the proposed methodology described previously.

Our analysis included 2,410 hospitals that are projected to be eligible for DSH in FY 2021. It did not include hospitals that terminated their participation from the Medicare program as of January 22, 2020, Maryland hospitals, new hospitals, MDHs, and SCHs that are expected to be paid based on their hospital-specific rates. The 27 hospitals participating in the Rural Community Hospital Demonstration Program were also excluded from this analysis, as participating hospitals are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. In addition, the data from merged or acquired hospitals were combined under the surviving hospital's CMS certification number (CCN), and the nonsurviving CCN was excluded from the analysis. The estimated impact of the proposed changes in Factors 1, 2, and 3 on uncompensated care payments across all hospitals projected to be eligible for DSH payments in FY 2021, by hospital characteristic, is presented in the following table.

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Modeled Uncompensated Care Payments for Estimated FY 2021 DSHs by Hospital Type: Model Uncompensated Care Payments ($ in Millions)* - from FY 2020 to FY 2021					
	Number of Estimated DSHs (1)	FY 2020 Final Rule Estimated Uncompensated Care Payments ($ in millions) (2)	FY 2021 Proposed Rule Estimated Uncompensated Care Payments ($ in millions) (3)	Dollar Difference: FY 2020 - FY 2021 ($ in millions) (4)	Percent Change** (5)
Total	2,410	$8,351	$7,817	-$534	-6.39%
By Geographic Location					
Urban Hospitals	1,923	7,826	7,352	-474	-6.05
Large Urban Areas	997	4,793	4,549	-244	-5.09
Other Urban Areas	926	3,033	2,803	-229	-7.57
Rural Hospitals	487	525	465	-60	-11.48
Bed Size (Urban)					
0 to 99 Beds	326	290	280	-10	-3.55
100 to 249 Beds	833	1,898	1,780	-118	-6.23
250+ Beds	764	5,637	5,292	-345	-6.12
Bed Size (Rural)					
0 to 99 Beds	365	290	249	-41	-14.13
100 to 249 Beds	109	190	168	-22	-11.44
250+ Beds	13	45	47	2	5.47
Urban by Region					
New England	93	251	213	-38	-15.01
Middle Atlantic	243	1,055	932	-123	-11.68
South Atlantic	312	1,972	1,910	-62	-3.13
East North Central	317	824	808	-17	-2.04
East South Central	127	496	469	-27	-5.50
West North Central	101	381	379	-2	-0.62
West South Central	245	1,701	1,542	-159	-9.37
Mountain	125	373	314	-58	-15.68
Pacific	320	663	685	22	3.31
Puerto Rico	40	109	100	-9	-7.84
Rural by Region					
New England	8	17	14	-2	-13.02
Middle Atlantic	25	20	15	-5	-25.58
South Atlantic	89	141	127	-14	-9.81

Modeled Uncompensated Care Payments for Estimated FY 2021 DSHs by Hospital Type: Model Uncompensated Care Payments ($ in Millions)* - from FY 2020 to FY 2021					
	Number of Estimated DSHs (1)	FY 2020 Final Rule Estimated Uncompensated Care Payments ($ in millions) (2)	FY 2021 Proposed Rule Estimated Uncompensated Care Payments ($ in millions) (3)	Dollar Difference: FY 2020 - FY 2021 ($ in millions) (4)	Percent Change** (5)
East North Central	71	61	59	-2	-3.37
East South Central	121	109	96	-13	-11.70
West North Central	32	32	31	-1	-3.77
West South Central	109	116	99	-17	-14.86
Mountain	27	23	18	-5	-22.13
Pacific	5	6	6	-1	-11.32
By Payment Classification					
Urban Hospitals	1,558	6,000	5,654	-346	-5.77
Large Urban Areas	863	3,896	3,711	-185	-4.76
Other Urban Areas	695	2,104	1,943	-161	-7.66
Rural Hospitals	852	2,351	2,163	-187	-7.97
Teaching Status					
Nonteaching	1,406	2,492	2,335	-157	-6.28
Fewer than 100 residents	750	2,856	2,676	-180	-6.30
100 or more residents	254	3,003	2,805	-197	-6.57
Type of Ownership					
Voluntary	1,450	4,557	4,305	-252	-5.52
Proprictary	580	1,247	1,155	-92	-7.41
Government	380	2,546	2,356	-190	-7.46
Medicare Utilization Percent* **					
0 to 25	524	3,227	3,031	-195	-6.06
25 to 50	1,642	4,896	4,576	-320	-6.54
50 to 65	215	215	200	-15	-6.76
Greater than 65	28	13	9	-4	-28.82

Source: Dobson | DaVanzo analysis of 2013 and 2017 Hospital Cost Reports.

*Dollar uncompensated care payments calculated by [0.75 * estimated section 1886(d)(5)(F) payments * Factor 2 * Factor 3]. When summed across all hospitals projected to receive DSH payments, uncompensated care payments are estimated to be $8,351 million in FY 2020 and $7,817 million in FY 2021.

** Percentage change is determined as the difference between Medicare uncompensated care payments modeled for this FY 2021 IPPS/LTCH PPS proposed rule (column 3) and Medicare uncompensated care payments modeled for the FY 2020 IPPS/LTCH PPS final rule correction notice (column 2) divided by Medicare uncompensated care payments modeled for the FY 2020 IPPS/LTCH PPS final rule correction notice (column 2) times 100 percent.

***Hospitals with missing or unknown Medicare utilization are not shown in table.

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The proposed changes in projected uncompensated care payments for FY 2021 in relation to the uncompensated care payments for FY 2020 are driven by a proposed decrease in Factor 1 and a proposed increase in Factor 2, as well as by a decrease in the number of hospitals projected to be eligible to receive DSH in FY 2021 relative to FY 2020. Proposed Factor 1 has decreased from $12.643 billion to $11.519 billion, while the proposed percent change in the percent of individuals who are uninsured (Factor 2) has increased from 67.14 percent to 67.86 percent. Based on the proposed changes in these two factors, the impact analysis found that, across all projected DSH eligible hospitals, proposed FY 2021 uncompensated care payments are estimated at approximately $7.817 billion, or a proposed decrease of approximately 6.39 percent from FY 2020 uncompensated care payments (approximately $8.351 billion). While these proposed changes would result in a net decrease in the amount available to be distributed in uncompensated care payments, the projected payment decreases vary by hospital type. This redistribution of uncompensated care payments is caused by proposed changes in Factor 3. As seen in the previous table, a percent change lower than negative 6.39 percent indicates that hospitals within the specified category are projected to experience a larger decrease in uncompensated care payments, on average, compared to the universe of projected FY 2021 DSH hospitals. Conversely, a percent change greater than negative 6.39 percent indicates that a hospital type is projected to have a smaller decrease than the overall average. Similarly, a positive percent change indicates an increase in uncompensated care payments. The variation in the distribution of payments by hospital characteristic is largely dependent on a given hospital's uncompensated care costs as reported in the Worksheet S–10, or number of Medicaid days and SSI days for Puerto Rico hospitals and Indian Health Service and Tribal hospitals, used in the Factor 3 computation.

Rural hospitals, in general, are projected to experience larger decreases in uncompensated care payments than their urban counterparts. Overall, rural hospitals are projected to receive an 11.48 percent decrease in uncompensated care payments, while urban hospitals are projected to receive a 6.05 percent decrease in uncompensated care payments.

By bed size, smaller rural hospitals are projected to receive the largest decreases in uncompensated care payments. Rural hospitals with 0–99 beds are projected to receive a 14.13 percent payment decrease, and rural hospitals with 100 – 249 beds are projected to receive an 11.44 percent

decrease. These decreases for smaller rural hospitals are greater than the overall hospital average. However, larger rural hospitals with 250+ beds are projected to receive a 5.47 percent payment increase. This is not consistent with the trend among urban hospitals, with the smallest urban hospitals (0–99 beds) projected to receive a decrease in uncompensated care payments of 3.55 percent, urban hospitals with 100 − 249 beds projected to receive a decrease of 6.23 percent, and larger urban hospitals with 250+ beds projected to receive a 6.12 percent decrease in uncompensated care payments, all of which are smaller decreases than the overall hospital average.

By region, rural hospitals are expected to receive larger than average decreases in uncompensated care payments in all Regions, except for rural hospitals in the East North Central and West North Central Regions, which are projected to receive smaller than average decreases. Regionally, urban hospitals are projected to receive a more varied range of payment changes. Urban hospitals in the New England, the Middle Atlantic, West South Central, and Mountain Regions, as well as urban hospitals in Puerto Rico, are projected to receive larger than average decreases in uncompensated care payments. Hospitals in the South Atlantic, East North Central, East South Central, and West North Central Regions are projected to receive smaller than average decreases in uncompensated care payments, while urban hospitals in the Pacific Region are projected to receive a 3.31 percent increase in uncompensated care payments.

By payment classification, although hospitals in urban areas overall are expected to receive a 5.77 percent decrease in uncompensated care payments, hospitals in large urban areas are expected to see a decrease in uncompensated care payments of 4.76 percent, while hospitals in other urban areas are expected to receive a decrease in uncompensated care payments of 7.66 percent. By payment classification, hospitals in rural areas are projected to receive a decrease of 7.97 percent.

Nonteaching hospitals are projected to receive a payment decrease of 6.28 percent, teaching hospitals with fewer than 100 residents are projected to receive a payment decrease of 6.30 percent, and teaching hospitals with 100+ residents have a projected payment decrease of 6.57 percent. All of these decreases are consistent with the overall hospital average. Proprietary and government hospitals are projected to receive larger than average decreases of 7.41 and 7.46 percent respectively, while voluntary hospitals are expected to receive a payment decrease of 5.52 percent. Hospitals with less than 65 percent Medicare utilization are projected to receive decreases in uncompensated care payments consistent with the overall hospital average percent change, while hospitals with greater than 65 percent Medicare utilization are projected to receive a larger decrease of 28.82 percent. Effects of Proposed Reductions Under the Hospital Readmissions Reduction Program for FY 2021.

In section IV.K. of the preamble of this proposed rule, we discuss our proposed policies for the FY 2021 Hospital Readmissions Reduction Program. This program requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions and procedures. The table and analysis in this proposed rule illustrate the estimated financial impact of the Hospital Readmission Reduction Program payment adjustment methodology by hospital characteristic. Hospitals are stratified into quintiles based on the proportion of dual-eligible stays among Medicare fee-for-service (FFS) and managed care stays between July 1, 2015 and June 30, 2018 (that is, the FY 2020 Hospital Readmissions Reduction Program's performance period). Hospitals' excess readmission ratios (ERRs) are assessed relative to their peer group median and a neutrality modifier is applied in the payment adjustment factor calculation to maintain budget neutrality. For the purpose of modeling the proposed FY 2021 payment adjustment factors for this proposed rule, we used the payment adjustment factors from the FY 2020 Hospital Readmissions Reduction Program and the FY 2020 Hospital IPPS proposed rule Impact File to analyze results by hospital characteristics. In the FY 2021 IPPS/LTCH PPS final rule, we will provide an updated estimate of the financial impact using the proportion of dual-eligibles, excess readmission ratios, and aggregate payments for each condition/procedure and all discharges for applicable hospitals from the FY 2021 Hospital Readmissions Reduction Program applicable period (that is, July 1, 2016 through June 30, 2019).

These analyses include 3,027 non-Maryland hospitals eligible to receive a penalty during the performance period. Hospitals are eligible to receive a penalty if they have 25 or more eligible discharges for at least one measure between July 1, 2015 and June 30, 2018. The second column in the table indicates the total number of non-Maryland hospitals with available data for each characteristic that have an estimated payment adjustment factor less than 1 (that is penalized hospitals).

The third column in the table indicates the percentage of penalized hospitals among those eligible to receive a penalty by hospital characteristic. For example, 82.80 percent of eligible hospitals characterized as non-teaching hospitals are expected to be penalized. Among teaching hospitals, 88.41 percent of eligible hospitals with fewer than 100 residents and 95.22 percent of eligible hospitals with 100 or more residents are expected to be penalized.

The fourth column in the table estimates the financial impact on hospitals by hospital characteristic. The table shows the share of penalties as a percentage of all base operating DRG payments for hospitals with each characteristic. This is calculated as the sum of penalties for all hospitals with that characteristic over the sum of all base operating DRG payments for those hospitals between October 1, 2017 and September 30, 2018 (FY 2018). For example, the penalty as a share of payments for urban hospitals is 0.69 percent. This means that total penalties for all urban hospitals are 0.69 percent of total payments for urban hospitals. Measuring the financial impact on hospitals as a percentage of total base operating DRG payments accounts for differences in the amount of base operating DRG payments for hospitals within the characteristic when comparing the financial impact of the program on different groups of hospitals.

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Estimated Percentage of Hospitals Penalized and Penalty as Share of Payments for FY 2021 Hospital Readmissions Reduction Program by Hospital Characteristic				
Hospital Characteristic	**Number of Eligible Hospitals[a]**	**Number of Penalized Hospitals[b]**	**Percentage of Hospitals Penalized[c] (%)**	**Penalty as a Share of Payments[d] (%)**
All Hospitals	3,027	2,583	85.33	0.69
Geographic Location[e] (n= 3,025)				
Urban hospitals	2,278	1,973	86.61	0.69
1-99 beds	528	385	72.92	0.88
100-199 beds	707	644	91.09	0.84
200-299 beds	410	366	89.27	0.79
300-399 beds	275	252	91.64	0.71
400-499 beds	139	128	92.09	0.54
500 or more beds	219	198	90.41	0.56
Rural hospitals	747	609	81.53	0.69
1-49 beds	285	205	71.93	0.60
50-99 beds	272	233	85.66	0.68
100-149 beds	106	94	88.68	0.71
150-199 beds	45	41	91.11	0.58
200 or more beds	39	36	92.31	0.81
Teaching Status[f] (n= 3,025)				
Non-teaching	1,954	1,618	82.80	0.82
Teaching, fewer than 100 residents	820	725	88.41	0.70
Teaching, 100 or more residents	251	239	95.22	0.49
Ownership Type (n= 3,005)				
Government	463	392	84.67	0.55
Proprietary	735	608	82.72	1.06
Voluntary	1,807	1,572	87.00	0.63
Safety-net Status[g] (n= 3,025)				
Safety-net hospitals	606	531	87.62	0.59
Non-safety-net hospitals	2,419	2,051	84.79	0.71
Disproportionate Share Hospital (DSH) Patient Percentage[h] (n= 3,025)				
0-24	1,231	1,009	81.97	0.79
25-49	1,441	1,266	87.86	0.64
50-64	190	174	91.58	0.66
65 and over	163	133	81.60	0.53
Medicare Cost Report (MCR) Percentage[i] (n= 3,011)				
0-24	470	400	85.11	0.52
25-49	2,087	1,794	85.96	0.69
50-64	395	336	85.06	0.97
65 and over	59	41	69.49	0.46
Region (n= 3,027)				
New England	127	112	88.19	0.90
Middle Atlantic	345	319	92.46	0.80
South Atlantic	508	465	91.54	0.76
East North Central	476	401	84.24	0.61
East South Central	282	250	88.65	0.92
West North Central	244	191	78.28	0.42
West South Central	465	395	84.95	0.71
Mountain	216	162	75.00	0.55
Pacific	364	288	79.12	0.50

Source: The table results are based on the FY 2020 payment adjustment factors of open, non-Maryland, subsection (d) hospitals only. The FY 2020 payment adjustment factors are based on discharges between July 1, 2015 and June 30, 2018 (the FY 2020

Hospital Readmissions Reduction Program performance period). Although data from all subsection (d) and Maryland hospitals are used in calculations of each hospital's ERR, this table does not include results for Maryland hospitals and hospitals that are not open as of the October 2019 public reporting open hospital list because these hospitals are not eligible for a penalty under the program. Hospitals are stratified into quintiles based on the proportion of Medicare FFS and managed care dual-eligible stays for the 3-year performance period. In the FY 2020 IPPS/LTCH PPS final rule, we finalized a revised definition of "dual-eligible," beginning with the FY 2021 program year, to allow for a 1-month lookback period in data sourced from the State Medicare Modernization Act (MMA) files to determine dual-eligible status for beneficiaries who die in the month of discharge. The calculations in this analysis use the prior definition of "dual-eligible" that determines dual-eligible status using the month of discharge for all beneficiaries in data sourced from the State MMA files. Hospital characteristics are from the FY 2020 Hospital IPPS proposed rule Impact File.

Note: After the release of the FY 2020 IPPS/LTCH PPS final rule, it was determined that the hospital-specific payments for Medicare Dependent Hospitals were not included in the calculation of the penalty as a share of payments presented in the FY 2020 IPPS/LTCH PPS final rule table (84 FR 42676 through 42677). This error only affected the penalty as a share of payments for the following hospital characteristics: urban hospitals with 1-99 beds, rural hospitals, rural hospitals with 1-49 beds, rural hospitals with 50-99 beds, non-safety-net hospitals, MCR percentage 50-64, and MCR percentage 65 and over (that is, the result for all hospitals and all other characteristics are not impacted). The penalty as a share of payments results in the FY 2020 IPPS/LTCH PPS final rule table were 0.01-0.02 percentage points lower than the corrected results. The previous table includes the corrected values for the penalty as a share of payments.

Footnotes:

[a] This column is the number of applicable hospitals within the characteristic that are eligible for a penalty (that is, they have 25 or more eligible discharges for at least one measure).

[b] This column is the number of applicable hospitals that are penalized (that is, they have 25 or more eligible discharges for at least one measure and an estimated payment adjustment factor less than 1) within the characteristic.

[c] This column is the percentage of applicable hospitals that are penalized among hospitals that are eligible to receive a penalty by characteristic.

[d] This column is calculated as the sum of all penalties for the group of hospitals with that characteristic divided by total base operating DRG payments for all those hospitals. MedPAR data from October 1, 2017 through September 30, 2018 (FY 2018) are used to estimate the total base operating DRG payments.

[e] The total number of hospitals with hospital characteristics data may not add up to the total number of hospitals because not all hospitals have data for all characteristics. All hospitals had information for region (n=3,027). Not all hospitals had data for geographic location (n=3,025; missing=2), teaching status (n=3,025; missing=2), ownership type (n=3,005; missing=22), safety-net status (n=3,025; missing=2), DSH patient percentage (n=3,025; missing=2), and MCR percentage (n=3,011; missing=16).

[f] A hospital is considered a teaching hospital if it has an Indirect Medical Education adjustment factor for Operation PPS (TCHOP) greater than zero.

[g] A hospital is considered a safety-net hospital if it is in the top DSH quintile.

[h] DSH patient percentage is the sum of the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

[i] MCR percentage is the percentage of total inpatient stays from Medicare patients.

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5. Effects of Requirements Under the FY 2021 Hospital Value-Based Purchasing (VBP) Program

In section IV.L. of the preamble of this proposed rule, we discuss the Hospital VBP Program under which the Secretary makes value-based incentive payments to hospitals based on their performance on measures during the performance period with respect to a fiscal year. These incentive payments will be funded for FY 2021 through a reduction to the FY 2021 base operating DRG payment amount for the discharge for the hospital for such fiscal year, as required by section 1886(o)(7)(B) of the Act. The applicable percentage for FY 2021 and subsequent years is 2 percent. The total amount available for value-based incentive payments must be equal to the total amount of reduced payments for all hospitals for the fiscal year, as estimated by the Secretary.

In section IV.L.1.b. of the preamble of this proposed rule, we estimate the available pool of funds for value-based incentive payments in the FY 2021 program year, which, in accordance with section 1886(o)(7)(C)(v) of the Act, will be 2.00 percent of base operating DRG payment amounts, or a total of approximately $1.9 billion. This estimated available pool for FY 2021 is based on the historical pool of hospitals that were eligible to participate in the FY 2020 program year and the payment information from the December 2019 update to the FY 2019 MedPAR file.

The estimated impacts of the FY 2021 program year by hospital characteristic, found in the table in this section, are based on historical TPSs. We used the FY 2020 program year's TPSs to calculate the proxy adjustment factors used for this impact analysis. These are the most recently available scores that hospitals were given an opportunity to review and correct. The proxy adjustment factors use estimated annual base operating DRG payment amounts derived from the December 2019 update to the FY 2019 MedPAR file. The proxy adjustment factors can be found in Table 16 associated with this proposed rule (available via the internet on the CMS website).

The impact analysis shows that, for the FY 2021 program year, the number of hospitals that are expected to receive an increase in their base operating DRG payment amount is higher than the number of hospitals that are expected to receive a decrease. On average, among urban hospitals, hospitals in the West North Central region are expected to have the largest positive percent change in base operating DRG payment amounts, and among rural hospitals, hospitals in the Pacific region are expected to have the largest positive percent change in base operating DRG payment amounts. Urban Middle Atlantic, Urban East South Central, and Urban West South Central regions are expected to experience, on average, a decrease in base operating DRG payment amounts. All other regions, both urban and rural, are expected to experience, on average, an increase in base operating DRG payment amounts.

As DSH patient percentage increases, the average percent change in base operating DRG payment amounts is expected to decrease. With respect to hospitals' Medicare utilization as a percent of inpatient days (MCR), as the MCR percent increases, the average percent change in base operating DRG payment amounts is expected to increase for MCR percent 0 to 65, but for MCR percent greater than 65, the average percent change in base operating DRG payment amounts is expected to decrease. On average, teaching hospitals are expected to have a decrease in base operating DRG payment amounts while non-teaching hospitals are expected to have an increase in base operating DRG payment amounts.

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Impact Analysis of Adjustments to Base Operating DRG Payment Amounts Resulting from the FY 2021 Hospital VBP Program		
	Number of Hospitals	Average Net Percentage Payment Adjustment
BY GEOGRAPHIC LOCATION:		
All Hospitals	**2,731**	**0.165**
Large Urban	1,056	0.083
Other Urban	1,047	0.082
Rural Area	628	0.443
Urban hospitals	***2,103***	**0.083**
0-99 beds	357	0.507
100-199 beds	697	0.149
200-299 beds	426	-0.044
300-499 beds	405	-0.152
500 or more beds	218	-0.141
Rural hospitals	***628***	**0.443**
0-49 beds	199	0.619
50-99 beds	251	0.527
100-149 beds	96	0.300
150-199 beds	44	-0.064
200 or more beds	38	-0.089
BY REGION:		
Urban By Region	**2,103**	**0.083**
New England	105	0.087
Middle Atlantic	278	-0.043
South Atlantic	376	0.003
East North Central	337	0.171
East South Central	127	-0.102
West North Central	131	0.348
West South Central	260	-0.010
Mountain	147	0.104
Pacific	342	0.212
Rural By Region	**628**	**0.443**
New England	19	0.500
Middle Atlantic	43	0.353
South Atlantic	99	0.325
East North Central	109	0.613
East South Central	113	0.250
West North Central	79	0.614
West South Central	96	0.299
Mountain	46	0.689
Pacific	24	0.730
BY MCR PERCENT:		
0-25	480	0.064
25-50	1,923	0.168
50-65	306	0.314
Over 65	20	0.093
Missing	2	-0.154
BY DSH PATIENT PERCENTAGE:		
0-25	1,058	0.271
25-50	1,353	0.112
50-65	178	0.046
Over 65	142	0.044
BY TEACHING STATUS:		
Non-Teaching	1,660	0.285
Teaching	1,071	-0.019

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Actual FY 2021 program year's TPSs will not be reviewed and corrected by hospitals until after the FY 2021 IPPS/LTCH PPS final rule has been published. Therefore, the same

historical universe of eligible hospitals and corresponding TPSs from the FY 2020 program year were used for the updated impact analysis in this proposed rule.

6. Effects of Requirements Under the HAC Reduction Program for FY 2021

In section IV.M. of the preamble of this proposed rule, we discuss the requirements for the HAC Reduction Program for FY 2021. In this proposed rule, we are not proposing to remove measures or adopt any new measures into the HAC Reduction Program.

a. Burden Associated With Validation

In section IV.M.6. of the preamble of this proposed rule, we propose to change the pool of hospitals selected for validation under the HAC Reduction Program from up to 600 hospitals to up to 400 hospitals, in alignment with the proposal under the Hospital IQR Program, as discussed in section VIII.A. of the preamble of this proposed rule. In section XI.B.7. of the preamble of this proposed rule, we update our burden estimates to reflect the proposal to decrease the number hospitals selected for validation and to reflect an updated median hourly wage, and the updated burden estimates show a decrease in burden of 14,400 hours and −$558,720 for each program year. We note the burden associated with these requirements is captured in an information collection request currently available for review and comment, OMB control number 0938–1352 (expires December 31, 2021).

We also note the burden associated with collecting and submitting data via the NHSN system is captured under a separate OMB control number, 0920–0666 (expiration date November 30, 2021), and therefore is not included in our burden estimates.

b. The Cumulative Effect of Program Measures and the Scoring Methodology

We are presenting the estimated impact of the FY 2021 HAC Reduction Program on hospitals by hospital characteristic. These FY 2021 HAC Reduction Program results were calculated using the same scoring methodology used in the FY 2020 HAC Reduction Program. Hospitals received a measure score for each measure, calculated as the hospital's Winsorized z-score for that measure relative to other hospitals in the program. Each hospital's Total HAC Score was calculated as the equally weighted average of the hospital's measure scores. The table in this section presents the estimated proportion of hospitals in the worst-performing quartile of Total HAC Scores by hospital characteristic.

Hospitals' CMS Patient Safety Indicator 90 (CMS PSI 90) measure results are based on Medicare fee-for-service (FFS) discharges from July 1, 2017 through June 30, 2019 and version 10.0 of the PSI software. Hospitals' measure results for Centers for Disease Control and Prevention (CDC) Central Line-Associated Bloodstream Infection (CLABSI), Catheter-Associated Urinary Tract Infection (CAUTI), Colon and Abdominal Hysterectomy Surgical Site Infection (SSI), Methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia, and *Clostridium difficile* Infection (CDI) are derived from standardized infection ratios (SIRs) calculated with hospital surveillance data reported to the National Healthcare Safety Network (NHSN) for infections occurring between January 1, 2017 and December 31, 2018.

To analyze the results by hospital characteristic, we used the FY 2020 final rule Impact File. This table includes 3,125 non-Maryland hospitals with a FY 2021 Total HAC Score. Maryland hospitals and hospitals without a Total HAC Score are excluded from the table. Of these 3,125 hospitals, 3,116 hospitals had information for geographic location with bed size, Safety-net status, disproportionate share hospital (DSH) percent, and teaching status; 3,125 had information on region, 3,088 had information for ownership; and 3,104 had information for Medicare Cost Report (MCR) percent. The first column presents a breakdown of each characteristic.

The second column in the table indicates the total number of non-Maryland hospitals with a FY 2021 Total HAC Score and available data for each characteristic. For example, with regard to teaching status, 2,020 hospitals are characterized as non-teaching hospitals, 846 are characterized as teaching hospitals with fewer than 100 residents, and 250 are characterized as teaching hospitals with at least 100 residents. This only represents a total of 3,116 hospitals because the other 9 hospitals are missing from the FY 2020 final rule Impact File.

The third column in the table indicates the number of hospitals for each characteristic that would be in the worst-performing quartile of Total HAC Scores. These hospitals would receive a payment reduction under the FY 2021 HAC Reduction Program. For example, with regard to teaching status, 443 hospitals out of 2,020 hospitals characterized as non-teaching hospitals would be subject to a payment reduction. Among teaching hospitals, 208 out of 846 hospitals with fewer than 100 residents and 122 out of 250 hospitals with 100 or more residents would be subject to a payment reduction.

The fourth column in the table indicates the proportion of hospitals for each characteristic that would be in the worst-performing quartile of Total HAC Scores and thus receive a payment reduction under the FY 2021 HAC Reduction Program. For example, 21.9 percent of the 2,020 hospitals characterized as non-teaching hospitals, 24.6 percent of the 846 teaching hospitals with fewer than 100 residents, and 48.8 percent of the 250 teaching hospitals with 100 or more residents would be subject to a payment reduction.

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Estimated Proportion of Hospitals in the Worst-Performing Quartile (>75th percentile) of the Total HAC Scores for the FY 2021 HAC Reduction Program by Hospital Characteristic			
Hospital Characteristic	**Number of Hospitals**	**Number of Hospitals in the Worst-Performing Quartile[a]**	**Percent of Hospitals in the Worst-Performing Quartile[b]**
Total[c]	3,125	780	25.0
By Geographic Location (n = 3,116)[d]			
Urban hospitals	**2,359**	**601**	**25.5**
1-99 beds	586	108	18.4
100-199 beds	715	169	23.6
200-299 beds	429	114	26.6
300-399 beds	267	79	29.6
400-499 beds	142	47	33.1
500 or more beds	220	84	38.2
Rural hospitals	**757**	**172**	**22.7**
1-49 beds	313	81	25.9
50-99 beds	262	53	20.2
100-149 beds	99	16	16.2
150-199 beds	45	13	28.9
200 or more beds	38	9	23.7
By Safety-Net Status[e] (n = 3,116)			
Non-safety net	2,482	557	22.4
Safety-net	634	216	34.1
By DSH Percent[f] (n = 3,116)			
0-24	1,294	264	20.4
25-49	1,448	372	25.7
50-64	201	71	35.3
65 and over	173	66	38.2
By Teaching Status[g] (n = 3,116)			
Non-teaching	2,020	443	21.9
Fewer than 100 residents	846	208	24.6
100 or more residents	250	122	48.8
By Ownership[h] (n = 3,088)			

Estimated Proportion of Hospitals in the Worst-Performing Quartile (>75th percentile) of the Total HAC Scores for the FY 2021 HAC Reduction Program by Hospital Characteristic

Hospital Characteristic	Number of Hospitals	Number of Hospitals in the Worst-Performing Quartile[a]	Percent of Hospitals in the Worst-Performing Quartile[b]
Voluntary	1,838	457	24.9
Proprietary	773	148	19.1
Government	477	160	33.5
By MCR Percent[i] (n = 3,104)			
0-24	563	168	29.8
25-49	2,100	490	23.3
50-64	382	95	24.9
65 and over	59	16	27.1
By Region[j] (n = 3,125)			
New England	130	43	33.1
Mid-Atlantic	351	95	27.1
South Atlantic	515	132	25.6
East North Central	484	116	24.0
East South Central	288	66	22.9
West North Central	248	65	26.2
West South Central	488	99	20.3
Mountain	230	52	22.6
Pacific	391	112	28.6

Source: FY 2021 HAC Reduction Program proposed rule Results are based on CMS PSI 90 data from July 2017 through June 2019 and CDC CLABSI, CAUTI, SSI, CDI, and MRSA results from January 2017 through December 2018. Hospital Characteristics are based on the FY 2020 final rule Impact File.

[a] This column is the number of non-Maryland hospitals with a Total HAC Score within the corresponding characteristic that are estimated to be in the worst-performing quartile.

[b] This column is the percent of non-Maryland hospitals within each characteristic that are estimated to be in the worst-performing quartile. The percentages are calculated by dividing the number of non-Maryland hospitals with a Total HAC Score in the worst-performing quartile by the total number of non-Maryland hospitals with a Total HAC Score within that characteristic.

[c] The number of non-Maryland hospitals with a FY 2021 Total HAC Score (N = 3,125). Note that not all hospitals have data for all hospital characteristics.

[d] The number of hospitals that had information for geographic location with bed size, Safety-net status, DSH percent, and teaching status (n = 3,116).

[e] A hospital is considered a Safety-net hospital if it is in the top quintile for DSH percent.

[f] The DSH patient percentage is equal to the sum of: (1) the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income; and (2) the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

[g] A hospital is considered a teaching hospital if it has an Indirect Medical Education (IME) adjustment factor for Operation PPS (TCHOP) greater than zero.

[h] Not all hospitals had data for Ownership (n = 3,088)

[i] Not all hospitals had data for MCR percent (n = 3,104).

[j] All hospitals had data for Region (n = 3,125)

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7. Proposed Policy Change Related to Medical Residents Affected by Residency Program or Teaching Hospital Closure

In section IV.N. of this proposed rule, we are proposing to amend the Medicare policy with regard to closing teaching hospitals and closing residency programs to address the needs of residents attempting to find alternative hospitals in which to complete their training and the incentives of home and receiving hospitals with regard to seamless Medicare IME and direct GME funding. There are no new Medicare funded slots being created by this proposal; as under current policy, the maximum number of FTE cap slots that may be transferred with displaced residents is the number equal to the closing hospital's IME and direct GME FTE caps. Additionally, all of the funding for these residents would eventually be transferred permanently to new hospitals under current law (section 5506 of the Affordable Care Act, which provides for permanent redistribution of slots due to hospital closure), regardless of whether or not we do or do not finalize these proposed changes. As a result, we believe that ultimately, there is no new cost generated for the Medicare program as a result of this proposal.

8. Effect of the Proposed Payment for Allogeneic Hematopoietic Stem Cell Acquisition Costs

Section 108 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94) provides that, effective for cost reporting periods beginning on or after October 1, 2020, payment to a subsection (d) hospital that furnishes an allogeneic hematopoietic stem cell transplant for hematopoietic stem cell acquisition shall be made on a reasonable cost basis, and that the Secretary shall specify the items included in such hematopoietic stem cell acquisition in rulemaking. This statutory provision also requires that, beginning in FY 2021, the payments made based on reasonable cost for

the acquisition costs of allogeneic hematopoietic stem cells be made in a budget neutral manner. Our proposals to implement section 108 of the Further Consolidated Appropriations Act, 2020 are discussed in section II.H. of the preamble of this proposed rule, including our proposed adjustment to the standardized amount to ensure the effects of the additional payments for allogeneic hematopoietic stem cell acquisition costs are budget neutral, as required under that law.

9. Effects of Implementation of the Rural Community Hospital Demonstration Program in FY 2021

In section IV.O. of the preamble of this proposed rule for FY 2021, we discussed our implementation and budget neutrality methodology for section 410A of Public Law 108–173, as amended by sections 3123 and 10313 of Public Law 111–148, and more recently, by section 15003 of Public Law 114–255, which requires the Secretary to conduct a demonstration that would modify payments for inpatient services for up to 30 rural hospitals.

Section 15003 of Public Law 114–255 requires the Secretary to conduct the Rural Community Hospital Demonstration for a 10-year extension period (in place of the 5-year extension period required by the Affordable Care Act), beginning on the date immediately following the last day of the initial 5-year period under section 410A(a)(5) of Public Law 108–173. Specifically, section 15003 of Public Law 114–255 amended section 410A(g)(4) of Public Law 108–173 to require that, for hospitals participating in the demonstration as of the last day of the initial 5-year period, the Secretary shall provide for continued participation of such rural community hospitals in the demonstration during the 10-year extension period, unless the hospital makes an election to discontinue participation. Furthermore, section 15003 of Public Law 114–255 requires that, during the second 5 years of the 10-year extension period, the Secretary shall provide for participation under the demonstration during the second 5 years of the 10-year extension period for hospitals that are not described in section 410A(g)(4) of Public Law 108–173.

Section 15003 of Public Law 114–255 also requires that no later than 120 days after enactment of Public Law 114–255 that the Secretary issue a solicitation for applications to select additional hospitals to participate in the demonstration program for the second 5 years of the 10-year extension period so long as the maximum number of 30 hospitals stipulated by Public Law 111–148 is not exceeded. Section 410A(c)(2) of Public Law 108–173 requires that in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented (budget neutrality).

In the preamble to this proposed rule, we described the terms of participation for the extension period authorized by Public Law 114–255. In the FY 2018 IPPS/LTCH PPS final rule, we finalized our policy with regard to the effective date for the application of the reasonable cost-based payment methodology under the demonstration for those among the hospitals that had previously participated and were choosing to participate in the second 5-year extension period. According to our finalized policy, each of these previously participating hospitals began the second 5 years of the 10-year extension period on the date immediately after the date the period of performance under the 5-year extension period ended. Seventeen of the 21 hospitals that completed their periods of participation under the extension period authorized by the Affordable Care Act elected to continue in the second 5-year extension period, while 13 additional hospitals were selected to participate. One of the hospitals selected in 2017 withdrew from the demonstration prior to beginning participation on July 1, 2018, while each of the remaining newly participating hospitals began its 5-year period of participation effective the start of the first cost reporting period on or after October 1, 2017. In addition, one among the previously participating hospitals closed effective January 2019, while one withdrew effective October 1, 2019. Thus, 27 hospitals are scheduled to participate in FY 2021.

In the FY 2018 IPPS/LTCH PPS final rule, we finalized the budget neutrality methodology in accordance with our policies for implementing the demonstration, adopting the general methodology used in previous years, whereby we estimated the additional payments made by the program for each of the participating hospitals as a result of the demonstration. In order to achieve budget neutrality, we adjusted the national IPPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we have applied budget neutrality across the payment system as a whole rather than across the participants of this demonstration. The language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration was not implemented, but does not identify the range across which aggregate payments must be held equal.

For this proposed rule, the resulting amount applicable to FY 2021 is $40,804,704, which we are including in the budget neutrality offset adjustment for FY 2021. This estimated amount is based on the specific assumptions regarding the data sources used, that is, recently available ''as submitted'' cost reports and historical and currently finalized update factors for cost and payment.

In previous years, we have incorporated a second component into the budget neutrality offset amounts identified in the final IPPS rules. As finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier, given year differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and we incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. We have calculated this difference for FYs 2005 through 2015 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

With the extension of the demonstration for another 5-year period, as authorized by section 15003 of Public Law 114–255, we will continue this general procedure. All finalized cost reports are not yet all available for the 19 hospitals that completed a cost reporting period beginning in FY 2016 according to the demonstration cost-based payment methodology. If the entire set of finalized cost reports is available in time, we will include within the budget neutrality adjustment in the FY 2021 IPPS/LTCH final rule the difference between the actual costs of the demonstration as determined from these cost reports and the estimated costs of the demonstration as determined in the FY 2016 IPPS final rule.

For this proposed rule for FY 2021, the total amount that we are applying to the national IPPS rates is $40,804,704.

10. Effects of Continued Implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration

In section VI.B.2. of the preamble of this proposed we discuss the implementation of the FCHIP demonstration, which allows eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care, and other health care services to Medicare beneficiaries in no more than four States. Budget neutrality estimates for the demonstration will be based on the demonstration period of August 1, 2016 through July 31, 2019. The demonstration includes three intervention prongs, under which specific waivers of Medicare payment rules will allow for enhanced payment: Telehealth, skilled nursing facility/nursing facility services, and ambulance services. These waivers were implemented with the goal of increasing access to care with no net increase in costs. (We also discussed this policy in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38294 through 38296), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41516 through 41517), and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42044 through 42701), but did not make any changes to the policy that was adopted in FY 2017.)

We specified the payment enhancements for the demonstration and selected CAHs for participation with the goal of maintaining the budget neutrality of the demonstration on its own terms (that is, the demonstration will produce savings from reduced transfers and admissions to other health care providers, thus offsetting any increase in payments resulting from the demonstration). However, because of the small size of this demonstration program and uncertainty associated with projected Medicare utilization and costs, in the FY 2017 IPPS/LTCH PPS final rule we adopted a contingency plan (81 FR 57064 through 57065) to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met. Accordingly, if analysis of claims data for the Medicare beneficiaries

receiving services at each of the participating CAHs, as well as of other data sources, including cost reports, shows that increases in Medicare payments under the demonstration during the 3-year period are not sufficiently offset by reductions elsewhere, we will recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide. The demonstration is projected to impact payments to participating CAHs under both Medicare Part A and Part B. Thus, in the event that we determine that aggregate payments under the demonstration exceed the payments that would otherwise have been made, we will recoup payments through reductions of Medicare payments to all CAHs under both Medicare Part A and Part B. Because of the small scale of the demonstration, it would not be feasible to implement budget neutrality by reducing payments only to the participating CAHs. Therefore, we will make the reduction to payments to all CAHs, not just those participating in the demonstration, because the FCHIP demonstration is specifically designed to test innovations that affect delivery of services by this provider category. As we explained in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065), we believe that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of the Act permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented, and does not identify the range across which aggregate payments must be held equal.

Under the policy adopted as stated in FY 2017 IPPS/LTCH PPS final rule, in the event the demonstration is found not to have been budget neutral, any excess costs will be recouped beginning in CY 2020. Based on the currently available data, the determination of budget neutrality results is preliminary and the amount of any reduction to CAH payments that would be needed in order to recoup excess costs under the demonstration remains uncertain. Therefore, we are proposing to revise the policy originally adopted in the FY 2017 IPPS/LTCH PPS final rule, to delay the implementation of any budget neutrality adjustment and will revisit this policy in rulemaking for FY 2022 when we expect to have complete data for the demonstration period. Since our data analysis is incomplete, it is not possible to determine the impact of this policy for any national payment system for FY 2021.

11. Effects of the Proposed Submission of Electronic Medical Records to Quality Improvement Organizations (QIOs)

In section IX.A. of this proposed rule, we specify our proposals regarding the reimbursement to providers, practitioners and institutions for electronic submission of patient records required for QIO purposes. Over the last several years, numerous healthcare providers subject to QIO review activity under § 476.78 and 480.111 have requested reimbursement for submitting requested patient records in an electronic format. However, our regulations concerning reimbursement to providers and practitioners for submitting patient records and information required for QIO review activity under § 476.78 only permitted reimbursement for records sent via photocopying and mailing or facsimile. This had the unintended consequence of discouraging providers from using the more efficient and cost effective means of submitting patient records and information to the QIOs in an electronic format solely because reimbursement was available only for patient records and information submitted via photocopying and mailing.

The proposed updates to the regulation respond to requests from providers, by addressing reimbursement for submitting records to the QIO in electronic format as well as by photocopying and mailing and facsimile. According to 2017 Office of National Coordinator survey result, 96 percent of all non-federal acute care hospitals possessed certified health IT. Ninety-nine percent of large hospitals (more than 300 beds) had certified health IT, while 97 percent of medium-sized hospitals (more than 100 beds) had certified health IT. Also nearly 9 in 10 (86 percent) of office-based physicians had adopted any EHR, and nearly 4 in 5 (80 percent) had adopted a certified EHR (*https://dashboard.healthit.gov/quickstats/quickstats.php*). Given the widespread adoption of the Certified Electronic Health Record Technology (CEHRT), we believe that the providers and QIOs now have the capacity to send and receive patient records in electronic format. In light of these facts, we believe that it would now be appropriate for us to require providers, practitioners and institutions to submit patient records to the QIOs in electronic format. Our proposal would also provide appropriate reimbursement for patient records submitted to the QIOs in an electronic format. We believe these changes would result in a large shift among providers, practitioners and institutions, which are subject to QIO review and which submit information and documents for the QIOs to perform their QIO functions under §§ 476.78 and 480.111, toward submitting patient records in electronic format. As discussed later in this section, we believe these proposals would help reduce CMS's costs for QIO labor associated with scanning and uploading patient records they receive by mail or facsimile, as well as reducing the time to complete QIO reviews as electronic records are generally easier to store and search. Thus, a requirement for providers to submit patient records to QIOs in electronic format would be advantageous for CMS. Providers and practitioners who are unable to send patient records to the QIOs in an electronic format would be able to obtain a waiver to permit them to submit records to the QIO via facsimile or photocopying and mailing under our proposal. We are proposing a new reimbursement rate for patient records submitted by facsimile or by photocopying and mailing to account for current wage and materials costs, and proposing a waiver process that is minimally burdensome for providers, practitioners, and institutions.

We expect that our proposal to require providers and practitioners to submit records to QIOs in and electronic format would have significant implications in terms of cost savings. Because CMS reimburses the QIOs directly for all payments to providers and practitioners for sending records to the QIOs and pays QIOs for their work, including the additional time and overhead expenses related to using paper records instead of electronic records. Therefore, any cost savings to the QIOs as a result of the adoption of electronic formats for submission of patient records would result in a cost savings to CMS. The less it costs to send records to the QIOs, the less CMS has to reimburse for those costs.

To estimate savings, we assumed 100% compliance and that CMS would receive, and therefore issue, zero requests for waivers. Although we assume that 20 percent of providers could seek a waiver, given the percentage of providers that currently have access to Certified Electronic Health Record Technology (CEHRT), the ultimate projection is that all providers will be able to submit patient records in electronic format in the future. We are interested in hearing from commenters whether this is a reasonable assumption.

We then estimate the total savings by subtracting the total cost of sending records electronically from the total cost of sending records by photocopying and mailing. Over the last 5 years, providers and practitioners have sent about 1.2 million patient records to the QIOs, totaling approximately 342 million pages of documents. Currently, providers are reimbursed at the rate of 12 cents per page, which results in a total reimbursement cost of about $41 million over 5 years. In contrast, under our current proposal, sending 1.2 million records electronically at a rate of reimbursement of $3 per record would amount to a total reimbursement cost of roughly $3.6 million. Subtracting $3.6 million (the estimated cost of sending records electronically over 5 years) from $41 (the cost of sending records by fax or by mail), would result in a total estimated savings to CMS of $37.4 million. We would save money on the efforts of the QIOs to scan and process the paper records before sending them on for review electronically. However, these longer-run savings would be preceded by short-run transition costs, and we request comment that would facilitate the estimation of upfront costs experienced by QIOs.

Based on our estimates for case volume set forth previously, and assuming the QIOs cost for scanning and labor is $0.10 per page, based on the information set out in Table 1 of this Appendix, we estimate that it would save CMS about $34.3 million if the agency no longer needed to scan 342 million pages of records. Savings in payments for the labor and materials costs provided to both providers and QIOs for photocopying, scanning, and uploading results in total savings to CMS of $71.8 million. Tables 2 and 3 of this Appendix illustrate the cost savings to CMS over 5 years.

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TABLE 1--ESTIMATED PROVIDERS REIMBURSEMENT AND LABOR COST SAVINGS FOR CMS

Estimated Payment to Providers						
QIO Review Type	5-Year Case Volume	Average Number of Pages per Medical Record	Total Number of Pages per Review Type	Estimated Cost for Electronic Transmission ($3 per Medical Record)	Labor Hours **	Estimated Total Cost of Photocopying (Based on $0.12 per page)
Hospital Discharge Appeal Review (Weichardt QOC)	159,343	408	65,011,944	$478,029	180,589	$7,801,433
Fee for Service Non-coverage Review (BIPA Appeals)	171,239	247	42,296,033	$513,717	117,489	$5,075,524
Medicare Advantage Non-coverage Review (Grijalva Appeals)	394,684	247	97,486,948	$1,184,052	270,797	$11,698,434
Hospital Inpatient Claims Reviews						
Hospital Inpatient Short Stay Claims Review	197,000	226	44,522,000	$591,000	123,672	$5,342,640
Hospital Inpatient DRG Claims Validation	156,129	509	79,469,661	$468,387	220,749	$9,536,359
Other Focused Claims Review	80,475	167	13,439,325	$241,425	37,331	$1,612,719
Total	1,158,870		342,225,911	$3,476,610		**$41,067,109** -$3,476,610
Savings					**950,628**	***$37,590,499**

*Postage cost is not included in this estimate.

** Labor Hours calculated based upon photocopying/scanning at the rate of 6 pages per minute (labor hour savings $= \frac{342,225,911}{6\,x60}) = 950,627.50$)

TABLE 2--ESTIMATED CMS COST SAVING FOR QIOs PROCESSING PAPER PATIENT RECORDS

QIO Review Type	5-Year Case Volume	Average Number of pages per Medical Record	Total Number of Pages per Review Type	QIO Labor Hours **	Estimated Total Cost for Scanning and Uploading by QIOs (Based on $0.10 per page)
Hospital Discharge Appeal Review (Weichardt QOC)	159,343	408	65,011,944	180,589	$6,501,194
Fee for Service Non-coverage Review (BIPA Appeals)	171,239	247	42,296,033	117,489	$4,229,603
Medicare Advantage Non-coverage Review (Grijalva Appeals)	394,684	247	97,486,948	270,797	$9,748,695
Hospital Inpatient Short Stay Claims Review	197,000	226	44,522,000	123,672	$4,452,200
Hospital Inpatient DRG Claims Validation	156,129	509	79,469,661	220,749	$7,946,966
Other Focused Claims Review	80,475	167	13,439,325	37,331	$1,343,933
Total	1,158,870		342,225,911		**$34,222,591**
Savings				**950,628**	**$34,222,591**

*** Cost of scanning and uploading of received medical records does not include cost of paper.

TABLE 3. ONE AND FIVE YEAR ESTIMATED CMS COST SAVINGS AND BURDEN ESTIMATE

	Savings		Burden (in hours)	
	1 Year	5 Years	1 Year	5 Years
Total cost and burden savings for CMS	$14,362,618.08	$71,813,090.42	380,251	1,901,255

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The BFCC–QIO contracts under the 12th scope of work currently have four task orders that are awarded on a staggered 5-year basis. Currently CMS has budgeted $95.8 million per year for each of the four BFCC–QIOs task orders, for an estimated 5-year cost of $479 million. We estimate that the costs of file transfer through photocopying and mailing, facsimile and in electronic formats would be a small fraction of the total operations budget of the QIOs. We believe that he proposed

changes would also benefit providers and practitioners in fulfilling their responsibilities under § 476.78 (obligating providers and practitioners to, among other things, furnish records to QIOs) and under § 480.111 (obligating institutions and practitioners to provide access, records and information to QIOs), by providing reimbursement for electronically providing copies of patient's medical records to the QIOs.

Given our estimate, discussed in section IX.A.2.d. of this proposed rule that an appropriate employee can reasonably photocopy 6 pages of documents per minute and scan documents at the rate of 6 documents per minute, we estimate that these proposed changes would save providers and CMS a total of approximately 1.9 million labor hours over 5 years. We expect these proposals would also result in a positive environmental impact by avoiding printing, photocopying, faxing, scanning, and recycling about 342.2 million pages of medical records by providers and QIOs over 5 years.

12. Effects of the Proposed Changes To Allow for Electronic Filing of Provider Reimbursement Review Board Appeals

In section IX.B. of the preamble of this proposed rule, we are proposing changes regarding PRRB appeals. We believe that these proposed changes would have minimal impact in terms of burden or cost on users. We also believe that requiring all parties involved in PRRB appeals to use OH CDMS would create efficiencies and reduce the burden and cost to external users in that, when a file or document is uploaded into the system and filed with the Board, the system simultaneously serves it on the opposing party. As a result, the system would eliminate the need to print documents and pay for postage for most submissions. Additionally, there is no material out-of-pocket direct cost or investment to utilize OH CDMS; parties do not need to purchase separate software. Finally, the required use of the system would also reduce the administrative burden on OH staff to enter data and scan correspondence, and would free up government resources to adjudicate cases and manage the docket. Similarly, it would enhance the PRRB's ability to strategically manage the PRRB's complex docket as it would provide better analytics for case management activities such as scheduling, jurisdictional and procedural reviews, and long-range docket planning. Last, the required use of the system would also reduce paper documents and the related costs associated with processing and securely storing the PRRB's records.

13. Effects of the Proposed Revisions of Medicare Bad Debt Policy

In section IX.C. of the preamble of this proposed rule, we are proposing clarifications and codification of certain longstanding Medicare bad debt reimbursement provisions and requirements for all Medicare providers, suppliers, and other entities eligible to receive Medicare payment for bad debt by revising 42 CFR 413.89, Bad debts, charity, and courtesy allowances. We are also proposing to codify our longstanding reasonable collection effort to require a Medicaid remittance advice (RA) for dual eligible beneficiaries. We are also seeking suggestions from stakeholders regarding the best alternative documentation to the Medicaid RA that a provider could obtain and submit to Medicare to evidence the State's Medicare cost sharing liability (or absence thereof) in instances where the State does not process a Medicare crossover claim and issue a Medicaid RA for certain dual eligible beneficiaries. In addition, we are recognizing the new Accounting Standard Update—Topic 606 for revenue recognition and classification of Medicare bad debts. We are also making a technical correction to the cross references in 42 CFR 412.622(b)(2)(i) and 42 CFR 417.536(g) to Medicare bad debt reimbursement policy. As a result of our proposals, there would be no costs to the Medicare Program and no increased burden placed upon providers, suppliers or other entities. As a result of our proposals, there would be a savings to the Medicare Program by the reduction of appeal and litigation costs. Providers would benefit and realize a burden reduction with our proposal to accept alternative documentation to evidence a provider's reasonable collection effort for certain dual eligible beneficiaries.

14. Effects of a Potential Market Based MS–DRG Relative Weight Methodology

In section IV.P.4. of the preamble of this proposed rule, we are seeking comment on a potential methodology for estimating the MS–DRG relative weights beginning in FY 2024 based on the median payer-specific negotiated charge information we are proposing to collect on the cost report and which we may consider adopting in the FY 2021 IPPS/LTCH PPS final rule. We note that the estimated total annual burden hours for this proposal are as follows: 3,189 hospitals times 15 hours per hospital equals 47,835 annual burden hours and $3,096,838. We refer readers to section XI.B.11. of the preamble of this proposed rule for further analysis of this assessment.

If CMS were to adopt a change to the MS–DRG relative weight methodology, we would apply a budget neutrality factor to ensure that the overall payment impact of any MS–DRG relative weight changes was budget neutral, as required by section 1886(d)(4)(C)(iii) of the Act and consistent with our current practice.

Once we have access to the proposed payer-specific negotiated charge information at the MS–DRG level, we will be able to more precisely estimate the potential payment impact of any potential changes to the MS–DRG relative weight methodology beginning in FY 2024. However, to explore the potential impacts more generally, we conducted a literature search to compare the payment rates of Medicare FFS, MA organizations, and other commercial payers. As noted in section IV.P.2.b. of the preamble of this proposed rule, Berenson et al.[518] surveyed senior hospital and health plan executives and found that MA plans nominally pay only 100 to 105 percent of traditional Medicare rates and, in real economic terms, possibly less. Respondents broadly identified three primary reasons for near–payment equivalence: Statutory and regulatory provisions that limit out-of-network payments to traditional Medicare rates, de facto budget constraints that MA plans face because of the need to compete with traditional Medicare and other MA plans, and a market equilibrium that permits relatively lower MA rates as long as commercial rates remain well above the traditional Medicare rates.

We next researched empirically based comparisons of Medicare FFS rates, MA organization rates, and rates of other commercial payers. Baker et al.[519] used data from Medicare and the Health Care Cost Institute (HCCI) to identify the prices paid for hospital services by FFS Medicare, MA plans, and commercial insurers in 2009 and 2012. They calculated the average price per admission, and its trend over time, in each of the three types of insurance for fixed baskets of hospital admissions across metropolitan areas. After accounting for differences in hospital networks, geographic areas, and case-mix between MA and FFS Medicare, they found that MA plans paid 5.6 percent less for hospital services compared to FFS Medicare. For the time period studied, the authors suggest that at least one channel through which MA plans paid lower prices was by obtaining greater discounts on types of FFS Medicare admissions that were known to have very short lengths-of-stay. They also found that the rates paid by commercial plans were much higher than those of either MA or FFS Medicare, and growing. At least some of this difference they indicated came from the much higher prices that commercial plans paid for profitable service lines.

Maeda and Nelson[520] also analyzed data from the HCCI in their research. They compared the hospital prices paid by MA organizations and commercial plans with Medicare FFS prices using 2013 claims from the HCCI. The HCCI claims were used to calculate hospital prices for private insurers, and Medicare's payment rules were used to estimate Medicare FFS prices. The authors focused on stays at acute care hospitals in metropolitan statistical areas (MSAs). They found MA prices to be roughly equal to Medicare FFS prices, on average, but commercial prices were 89 percent higher than FFS prices. In addition, commercial prices varied greatly across and within MSAs, but MA prices varied much less. The authors considered their results generally consistent with the Baker et al. study findings in that hospital payments by MA plans were much more similar to Medicare FFS levels than they were to commercial payment levels, although they noted that

[518] Berenson RA, Sunsine JH, Helms D, Lawton E. Why Medicare Advantage plans pay hospitals traditional Medicare prices. *Health Aff (Millwood).* 2015;34(8):1289–1295.

[519] Baker LC, Bundorf MK, Devlin AM, Kessler DP. Medicare Advantage plans pay less than traditional Medicare pays. *Health Aff (Millwood).* 2016;35(8):1444–1451.

[520] Maeda JLK, Nelson L. How Do the Hospital Prices Paid by Medicare Advantage Plans and Commercial Plans Compare with Medicare Fee-for-Service Prices? *The Journal of Health Care Organization, Provision, and Financing.* 2018;55(1–8)

they used slightly different methods to calculate Medicare FFS prices.

In their study, Maeda and Nelson also examined whether the ratio of MA prices to FFS prices varied across DRGs to assess whether there were certain DRGs for which MA plans tended to pay more or less than FFS. They ranked the ratio of MA prices to FFS prices and adjusted for outlier payments. They found that there were some DRGs where the average MA price was much higher than FFS and there were some DRGs where the average MA price was a bit lower than FFS. For example, for the time period in question on average MA plans paid 129 percent more than FFS for rehabilitation stays (DRG 945), 33 percent more for depressive neuroses (DRG 881), and 27 percent more for stays related to psychoses (DRG 885). But MA plans paid an average of 9 percent less than FFS for stays related to pathological fractures (DRG 542) and wound debridement and skin graft (DRG 464) (see Online Appendix Table 5 from their study). The authors state these results suggest that there may be certain services where MA plans pay more than FFS, possibly because the FFS rate for those services is too low, but there may be other services where MA plans pay less than FFS, possibly because the FFS rate for those DRGs is too high.

As described previously, this body of research suggests that while the payer-specific charges negotiated between hospitals and MA organizations are generally well-correlated with Medicare IPPS payment rates, there may be instances where those negotiated charges may reflect the relative hospital resources used within an MS–DRG differently than our current cost-based methodology. Payer-specific charges negotiated between hospitals and commercial payers are generally not as well-correlated with Medicare IPPS payment rates.

As previously noted, once we have access to the proposed payer-specific negotiated charge information at the MS–DRG level, we can more precisely estimate the potential payment impact of any potential changes to the MS–DRG relative weight methodology beginning in FY 2024. As part of our request for comments on this potential new market-based methodology for estimating the MS–DRG relative weights, we also welcome analysis from researchers and others who may currently have access to payer-specific negotiated charge data, regarding the potential impact of the use of such data on the MS–DRG relative weights. As under the current methodology, the impact of any MS–DRG relative weight changes on an individual hospital would depend on the mix of services provided by that particular hospital.

I. Effects of Proposed Changes in the Capital IPPS

1. General Considerations

For the impact analysis presented in this section, we used data from the December 2019 update of the FY 2019 MedPAR file and the December 2019 update of the Provider-Specific File (PSF) that was used for payment purposes. Although the analyses of the proposed changes to the capital prospective payment system do not incorporate cost data, we used the December 2019 update of the most recently available hospital cost report data (FYs 2017 and 2018) to categorize hospitals. Our analysis has several qualifications. We use the best data available and make assumptions about case-mix and beneficiary enrollment, as described later in this section.

Due to the interdependent nature of the IPPS, it is very difficult to precisely quantify the impact associated with each proposed change. In addition, we draw upon various sources for the data used to categorize hospitals in the tables. In some cases (for instance, the number of beds), there is a fair degree of variation in the data from different sources. We have attempted to construct these variables with the best available sources overall. However, it is possible that some individual hospitals are placed in the wrong category.

Using cases from the December 2019 update of the FY 2019 MedPAR file, we simulated payments under the capital IPPS for FY 2020 and the proposed payments for FY 2021 for a comparison of total payments per case. Short-term, acute care hospitals not paid under the general IPPS (for example, hospitals in Maryland) are excluded from the simulations.

The methodology for determining a capital IPPS payment is set forth at § 412.312. The basic methodology for calculating the proposed capital IPPS payments in FY 2021 is as follows:

(Standard Federal rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH adjustment factor + IME adjustment factor, if applicable).

In addition to the other adjustments, hospitals may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. We modeled payments for each hospital by multiplying the capital Federal rate by the GAF and the hospital's case-mix. Then we added estimated payments for indirect medical education, disproportionate share, and outliers, if applicable. For purposes of this impact analysis, the model includes the following assumptions:

- The capital Federal rate was updated, beginning in FY 1996, by an analytical framework that considers changes in the prices associated with capital-related costs and adjustments to account for forecast error, changes in the case-mix index, allowable changes in intensity, and other factors. As discussed in section III.A.1. of the Addendum to this proposed rule, the proposed update to the capital Federal rate is 1.5 percent for FY 2021.
- In addition to the proposed FY 2021 update factor, the proposed FY 2021 capital Federal rate was calculated based on a proposed GAF/DRG budget neutrality adjustment factor of 0.9983 and a proposed outlier adjustment factor of 0.9461.

2. Results

We used the payment simulation model previously described in section I.I. of Appendix A of this proposed rule to estimate the potential impact of the proposed changes for FY 2021 on total capital payments per case, using a universe of 3,199 hospitals. As previously described, the individual hospital payment parameters are taken from the best available data, including the December 2019 update of the FY 2019 MedPAR file, the December 2019 update to the PSF, and the most recent cost report data from the December 2019 update of HCRIS. In Table III, we present a comparison of estimated proposed total payments per case for FY 2020 and estimated total payments per case for FY 2021 based on the proposed FY 2021 payment policies. Column 2 shows estimates of payments per case under our model for FY 2020. Column 3 shows estimates of proposed payments per case under our model for FY 2021. Column 4 shows the proposed total percentage change in payments from FY 2020 to FY 2021. The change represented in Column 4 includes the proposed 1.5 percent update to the capital Federal rate and other proposed changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) Geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, capital payments per case in FY 2021 are expected to increase as compared to capital payments per case in FY 2020. This expected increase overall is primarily due to the proposed 1.5 percent update to the capital Federal rate for FY 2021, in conjunction with estimated changes in outlier payments and DSH payments. Under § 412.320, in order to receive capital DSH payments a hospital must be located in an urban area for payment purposes and have 100 or more beds. As discussed in section III.A.2. of the preamble of this proposed rule, there are counties that would become rural if we finalize our proposal to implement the revised OMB delineations, and therefore, hospitals in those areas (that have 100 or more beds) would no longer be eligible for capital DSH payments beginning in FY 2021. In general, regional variations in estimated capital payments per case in FY 2021 as compared to capital payments per case in FY 2020 are primarily due to changes in GAFs, and are generally consistent with the projected changes in payments due to proposed changes in the wage index (and proposed policies affecting the wage index), as shown in Table I in section I.G. of this Appendix A.

The net impact of these proposed changes is an estimated 0.62 percent increase in capital payments per case from FY 2020 to FY 2021 for all hospitals (as shown in Table III).

The geographic comparison shows that, on average, hospitals in both urban and rural classifications would experience an increase in capital IPPS payments per case in FY 2021 as compared to FY 2020. Capital IPPS payments per case would increase by an estimated 0.5 percent for hospitals in urban areas while payments to hospitals in rural areas would increase by 0.7 percent in FY 2020 to FY 2021.

The comparisons by region show that the estimated changes in capital payments per case from FY 2020 to FY 2021 would increase in nearly all urban areas, ranging from a 0.1 percent increase for the South Atlantic region to a 1.2 percent increase for the Pacific region. We estimate a decrease for the Mountain region of 0.4 percent in capital

payments per case from FY 2020 to FY 2021. Similarly, nearly all rural regions are expected to increase in capital payments per case from FY 2020 to FY 2021, ranging from 0.3 percent for the South Atlantic and Mountain rural regions to a 1.6 percent increase for the East North Central rural region. We estimate no change in capital payments per case from FY 2020 to FY 2021 for the West North Central rural region. These regional differences are primarily due to the changes in the proposed GAFs and estimated changes in outlier payments.

Hospitals of all types of ownership (that is, voluntary hospitals, government hospitals, and proprietary hospitals) are expected to experience an increase in capital payments per case from FY 2020 to FY 2021. The projected increase in capital payments for government hospitals is estimated to be 0.9 percent. Proprietary hospitals and voluntary hospitals are both expected to experience an increase in capital IPPS payments of 0.5 percent.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2021. Reclassification for wage index purposes also affects the GAFs because that factor is constructed from the hospital wage index. To present the effects of the hospitals being reclassified as of the publication of this proposed rule for FY 2021, we show the proposed average capital payments per case for reclassified hospitals for FY 2021. Urban reclassified hospitals are expected to experience a decrease in capital payments of 0.1 percent; urban nonreclassified hospitals are expected to experience an increase in capital payments of 1.0 percent. The estimated percentage increase for rural reclassified hospitals is 0.9 percent, and for rural nonreclassified hospitals, the estimated percentage increase in capital payments is 0.8 percent. The estimated percentage decrease for All 401 reclassified hospitals is 0.6 percent, which is mostly due to the changes in the proposed GAFs.

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TABLE III.—COMPARISON OF TOTAL PAYMENTS PER CASE
[FY 2020 PAYMENTS COMPARED TO PROPOSED FY 2021 PAYMENTS]

	Number of hospitals	Average FY 2020 payments/ case	Proposed Average FY 2021 payments/ case	Change
All hospitals	3,199	975	981	0.6
By Geographic Location:				
Urban Hospitals	2,459	1,009	1,014	0.5
Rural areas	740	667	672	0.7
Urban hospitals				
0-99 beds	634	812	815	0.4
100-199 beds	752	857	861	0.5
200-299 beds	438	935	938	0.3
300-499 beds	414	1,013	1,019	0.6
500 or more beds	221	1,209	1,218	0.7
Rural hospitals				
0-49 beds	300	568	571	0.5
50-99 beds	259	622	627	0.8
100-149 beds	98	661	664	0.5
150-199 beds	44	708	715	1.0
200 or more beds	39	790	801	1.4
By Region:				
Urban by Region				
New England	112	1,085	1,095	0.9
Middle Atlantic	305	1,114	1,121	0.6
South Atlantic	402	887	888	0.1
East North Central	380	960	963	0.3
East South Central	144	860	866	0.7
West North Central	159	994	1,001	0.7
West South Central	364	925	934	1.0
Mountain	172	1,033	1,029	-0.4
Pacific	371	1,291	1,306	1.2
Rural by Region				
New England	19	924	937	1.4
Middle Atlantic	50	644	652	1.2
South Atlantic	115	620	622	0.3
East North Central	114	669	680	1.6
East South Central	144	626	631	0.8
West North Central	89	698	698	0.0
West South Central	136	597	601	0.7
Mountain	49	759	761	0.3
Pacific	24	865	873	0.9
By Payment Classification:				
Teaching Status:				
Non-teaching	2,043	821	823	0.2
Fewer than 100 Residents	901	931	937	0.6
100 or more Residents	255	1,350	1,361	0.8
Urban DSH:				
100 or more beds	1,273	1,030	1,042	1.2
Less than 100 beds	352	746	747	0.1
Rural DSH:				
Sole Community (SCH/EACH)	257	694	698	0.6

TABLE III.—COMPARISON OF TOTAL PAYMENTS PER CASE
[FY 2020 PAYMENTS COMPARED TO PROPOSED FY 2021 PAYMENTS]

	Number of hospitals	Average FY 2020 payments/ case	Proposed Average FY 2021 payments/ case	Change
Referral Center (RRC/EACH)	538	972	971	-0.1
Other Rural:				
100 or more beds	59	951	910	-4.3
Less than 100 beds	215	557	561	0.7
Urban teaching and DSH:				
Both teaching and DSH	738	1,098	1,111	1.2
Teaching and no DSH	70	959	967	0.8
No teaching and DSH	887	868	874	0.7
No teaching and no DSH	333	875	880	0.6
Rural Hospital Types:				
Non special status hospitals	190	876	847	-3.3
RRC/EACH	471	1,000	999	-0.1
SCH/EACH	304	760	763	0.4
Medicare-dependent hospitals (MDH)	146	590	593	0.5
SCH, RRC and EACH	148	798	804	0.8
MDH, RRC and EACH	24	654	658	0.6
Hospitals Reclassified by the Medicare Geographic Classification Review Board:				
FY2021 Reclassifications:				
All Urban Reclassified	778	1,013	1,012	-0.1
All Urban Non-Reclassified	1,693	1,005	1,015	1.0
All Rural Reclassified	310	686	692	0.9
All Rural Non-Reclassified	418	638	643	0.8
All Section 401 Reclassified Hospitals	485	1,014	1,008	-0.6
Other Reclassified Hospitals (Section 1886(d)(8)(B))	54	660	666	0.9
Type of Ownership:				
Voluntary	1,884	987	992	0.5
Proprietary	826	888	892	0.5
Government	488	1,029	1,038	0.9
Medicare Utilization as a Percent of Inpatient Days:				
0-25	601	1,119	1,126	0.6
25-50	2,108	970	976	0.6
50-65	391	784	787	0.4
Over 65	64	621	620	-0.2

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J. Proposed Effects of Payment Rate Changes and Policy Changes Under the LTCH PPS

1. Introduction and General Considerations

In section VII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule, we set forth the annual update to the payment rates for the LTCH PPS for FY 2021. In the preamble of this proposed rule, we specify the statutory authority for the provisions that are presented, identify the policies for FY 2021, and present rationales for our decisions as well as alternatives that were considered. In this section of Appendix A to this proposed rule, we discuss the impact of the changes to the payment rate, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this proposed rule in terms of their estimated fiscal impact on the Medicare budget and on LTCHs.

There are 360 LTCHs included in this impact analysis. We note that, although there are currently approximately 366 LTCHs, for purposes of this impact analysis, we excluded the data of all-inclusive rate providers consistent with the development of the FY 2021 MS–LTC–DRG relative weights (discussed in section VII.B.3.c. of the preamble of this proposed rule). In the impact analysis, we used the payment rate, factors, and policies presented in this proposed rule, the proposed 2.5 percent annual update to the LTCH PPS standard Federal payment rate, the permanent one-time budget neutrality adjustment factor for the estimated cost of eliminating the 25-percent threshold policy in FY 2021 as discussed in section VII.D. of the preamble of this proposed rule, the proposed update to the MS–LTC–DRG classifications and relative weights, the proposed update to the wage index values, labor-related share, and changes to the geographic labor-market area designations, and the proposed 5-percent cap transition policy, and the best available claims and CCR data to estimate the change in payments for FY 2021.

Under the dual rate LTCH PPS payment structure, payment for LTCH discharges that

meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) is based on the LTCH PPS standard Federal payment rate. Consistent with the statute, the site neutral payment rate is the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), including any applicable outlier payments as specified in § 412.525(a), reduced by 4.6 percent for FYs 2018 through 2026; or 100 percent of the estimated cost of the case as determined under § 412.529(d)(2). In addition, there are two separate high cost outlier targets—one for LTCH PPS standard Federal payment rate cases and one for site neutral payment rate cases. The statute also establishes a transitional payment method for cases that are paid the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 through FY 2019. For FY 2021, we expected no site neutral payment rate cases would still be eligible for the transitional payment method since it only applies to those site neutral payment rate cases whose discharges occur during a LTCH's cost reporting period that begins before October 1, 2019. Site neutral payment rate cases whose discharges from an LTCH occur during the LTCH's cost reporting period that begins on or after October 1, 2019 are paid the site neutral payment rate amount determined under § 412.522(c)(1).

Based on the best available data for the 360 LTCHs in our database that were considered in the analyses used for this proposed rule, we estimate that overall LTCH PPS payments in FY 2021 will decrease by approximately 0.9 percent (or approximately $36 million) based on the rates and factors presented in section VII. of the preamble and section V. of the Addendum to this proposed rule.

The applicability of this transitional payment method for site neutral payment rate cases is dependent upon both the discharge date of the case and the start date of the LTCH's FY 2020 cost reporting period. The statutory transitional payment method for cases that are paid the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2019 uses a blended payment rate, which is determined as 50 percent of the site neutral payment rate amount for the discharge and 50 percent of the LTCH PPS standard Federal prospective payment rate amount for the discharge (§ 412.522(c)(3)). There are LTCHs that have a cost reporting period beginning during FY 2019 that includes discharges that occur during Federal FY 2020. For example, an LTCH with a January 1, 2020 through December 31, 2020 cost reporting period would have 9 months of discharges that occur during Federal FY 2020 (that is, discharges that occur from January 1, 2020 through September 30, 2020).

Therefore, when estimating FY 2020 LTCH PPS payments for site neutral payment rate cases for this impact analysis, because the statute specifies that the site neutral payment rate effective date for a given LTCH is based on the date that the LTCH's cost reporting period begins during FY 2020, we included an adjustment to account for this rolling effective date, consistent with the general approach used for the LTCH PPS impact analysis presented in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 49831). This approach accounts for the fact that site neutral payment rate cases in FY 2020 that are in an LTCH's cost reporting period that begins before October 1, 2019 continue to be paid under the transitional payment method until the start of the LTCH's first cost reporting period beginning on or after October 1, 2019. Site neutral payment rate cases whose discharges from LTCHs occurring during an LTCH's cost reporting period that begins on or after October 1, 2019 will no longer be paid under the transitional payment method and will instead be paid the site neutral payment rate amount as determined under § 412.522(c)(1).

For purposes of this impact analysis, to estimate total FY 2020 LTCH PPS payments for site neutral payment rate cases, we are proposing to use the same general approach as was used in the FY 2016 IPPS/LTCH PPS proposed rule with modifications to account for the rolling end date to the transitional blended payment rate in FY 2020 instead of the rolling effective date for implementation of the transitional site neutral payment rate in FY 2016. (We note, this is the same approach as was used in the FY 2018 IPPS/LTCH PPS proposed and final rules, which was prior to the extension of the transitional blended payment for LTCH cost reporting periods beginning in FY 2018 and FY 2019 provided by the provisions of section 51005(a) of the Bipartisan Budget Act of 2018 (Pub. L. 115–123). In summary, under this approach, we grouped LTCHs based on the quarter their cost reporting periods will begin during FY 2020. For example, LTCHs with cost reporting periods that begin during October through December 2020 begin during the first quarter of FY 2020. For LTCHs grouped in each quarter of FY 2020, we modeled those LTCHs' estimated FY 2020 site neutral payment rate payments under the transitional blended payment rate based on the quarter in which the LTCHs in each group will continue to be paid the transitional payment method for the site neutral payment rate cases.

For purposes of this estimate, then, we assume the cost reporting period is the same for all LTCHs in each of the quarterly groups and that this cost reporting period begins on the first day of that quarter. (For example, the first group consists of 36 LTCHs whose cost reporting period begins in the first quarter of FY 2020 so that, for purposes of this estimate, we assume all 36 LTCHs began their FY 2020 cost reporting period on October 1, 2019.) Second, we estimated the proportion of FY 2020 site neutral payment rate cases in each of the quarterly groups, and we then assume this proportion is applicable for all four quarters of FY 2020. (For example, as discussed in more detail later in this section, we estimate the first quarter group will discharge 7.9 percent of all FY 2020 site neutral payment rate cases; and therefore, we estimate that group of LTCHs will discharge 7.9 percent of all FY 2020 site neutral payment rate cases in each quarter of FY 2020.) Then, we modeled estimated FY 2020 payments on a quarterly basis under the LTCH PPS standard Federal payment rate based on the assumptions described previously. We continue to believe that this approach is a reasonable means of taking the rolling effective date into account when estimating FY 2020 payments.

For purposes of this impact analysis, to estimate total FY 2021 LTCH PPS payments for site neutral payment rate cases, the transitional blended payment rate was not applied to such cases because all discharges in FY 2021 are either in the LTCH's cost reporting period that began during FY 2020 or in the LTCH's cost reporting period that will begin during FY 2021. Site neutral payment rate cases whose discharges from an LTCH occur during the LTCH's cost reporting period that begins on or after October 1, 2019 are paid the site neutral payment rate amount determined under § 412.522(c)(1).

Based on the fiscal year begin date information in the December 2019 update of the provider specific file (PSF) and the LTCH claims from the December 2019 update of the FY 2019 MedPAR files for the 360 LTCHs in our database used for this proposed rule, we found the following: 7.9 percent of site neutral payment rate cases are from 36 LTCHs whose cost reporting periods began during the first quarter of FY 2020; 26.5 percent of site neutral payment rate cases are from 84 LTCHs whose cost reporting periods will begin in the second quarter of FY 2020; 9.4 percent of site neutral payment rate cases are from 48 LTCHs whose cost reporting periods will begin in the third quarter of FY 2020; and 56.2 percent of site neutral payment rate cases are from 188 LTCHs whose cost reporting periods will begin in the fourth quarter of FY 2020. (We note, four of the 360 LTCHs in our database used for this proposed rule did not have any site neutral payment rate cases.) Therefore, the following percentages apply in the approach described previously:

- *First Quarter FY 2020:* 7.9 percent of site neutral payment rate cases (that is, the percentage of discharges from LTCHs whose FY 2020 cost reporting period began in the first quarter of FY 2020) are no longer eligible for the transitional blended payment method, while the remaining 92.1 percent of site neutral payment rate discharges are eligible to be paid under the transitional payment method.
- *Second Quarter FY 2020:* 34.4 percent of site neutral payment rate second quarter discharges (that is, the percentage of discharges from LTCHs whose FY 2020 cost reporting period that begins in the first or second quarter of FY 2020) are no longer eligible for the transitional blended payment method, while the remaining 65.6 percent of site neutral payment rate second quarter discharges are eligible to be paid under the transitional payment method.
- *Third Quarter FY 2020:* 43.8 percent of site neutral payment rate third quarter discharges (that is, the percentage of discharges from LTCHs whose FY 2020 cost reporting period that begins in the first, second, or third quarter of FY 2020) are no longer eligible for the transitional blended payment method while the remaining 56.2 percent of site neutral payment rate third quarter discharges are eligible to be paid under the transitional payment method.
- *Fourth Quarter FY 2021:* 100.0 percent of site neutral payment rate fourth quarter

discharges (that is, the percentage of discharges from LTCHs whose FY 2020 cost reporting period that begins in the first, second, third, or fourth quarter of FY 2020) are no longer eligible for the transitional blended payment method.

Based on the FY 2019 LTCH cases that were used for the analysis in this proposed rule, approximately 25 percent of those cases were classified as site neutral payment rate cases (that is, 25 percent of LTCH cases did not meet the patient-level criteria for exclusion from the site neutral payment rate). Our Office of the Actuary currently estimates that the percent of LTCH PPS cases that will be paid at the site neutral payment rate in FY 2021 will not change significantly from the most recent historical data. Taking into account the transitional blended payment rate and other changes that will apply to the site neutral payment rate cases in FY 2021, we estimate that aggregate LTCH PPS payments for these site neutral payment rate cases will decrease by approximately 21 percent (or approximately $105 million). We note, we estimate payments to site neutral payment rate cases in FY 2021 represent approximately 10 percent of estimated aggregate FY 2021 LTCH PPS payments.

Based on the FY 2019 LTCH cases that were used for the analysis in this proposed rule, approximately 75 percent of LTCH cases will meet the patient-level criteria for exclusion from the site neutral payment rate in FY 2021, and will be paid based on the LTCH PPS standard Federal payment rate for the full year. We estimate that total LTCH PPS payments for these LTCH PPS standard Federal payment rate cases in FY 2021 will increase approximately 2.1 percent (or approximately $69 million). This estimated increase in LTCH PPS payments for LTCH PPS standard Federal payment rate cases in FY 2021 is primarily due to the proposed 2.5 percent annual update to the LTCH PPS standard Federal payment rate for FY 2021 and the projected 0.5 percent decrease in high cost outlier payments discussed in section V.D.3.b.(3). of the Addendum to this proposed rule.

Based on the 360 LTCHs that were represented in the FY 2019 LTCH cases that were used for the analyses in this proposed rule presented in this Appendix, we estimate that aggregate FY 2020 LTCH PPS payments will be approximately $3.797 billion, as compared to estimated aggregate FY 2021 LTCH PPS payments of approximately $3.761 billion, resulting in an estimated overall decrease in LTCH PPS payments of approximately $36 million. As discussed earlier, this estimated decrease in payments is primarily due to the rolling end to the statutory transitional blended payment rate for site neutral payment rate cases. We also note that the estimated $36 million decrease in LTCH PPS payments in FY 2021 does not reflect changes in LTCH admissions or case-mix intensity, which will also affect the overall payment effects of the policies in this proposed rule.

The LTCH PPS standard Federal payment rate for FY 2020 is $42,677.64. For FY 2021, we are proposing to establish an LTCH PPS standard Federal payment rate of $43,849.28 which reflects the proposed 2.5 percent annual update to the LTCH PPS standard Federal payment rate, the incremental change in the one-time budget neutrality adjustment factor of 0.991249 for eliminating the 25-percent threshold policy in FY 2021 as discussed in section VII.D. of the preamble of this proposed rule, and the proposed budget neutrality factor for general updates to the area wage level adjustment of 1.0018755 (discussed in section V.B.6. of the Addendum to this proposed rule). For LTCHs that fail to submit data for the LTCH QRP, in accordance with section 1886(m)(5)(C) of the Act, we are proposing an LTCH PPS standard Federal payment rate of $42,993.68. This LTCH PPS standard Federal payment rate reflects the updates and factors previously described, as well as the required 2.0 percentage point reduction to the annual update for failure to submit data under the LTCH QRP. We note that the factors previously described to determine the FY 2021 LTCH PPS standard Federal payment rate are applied to the FY 2020 LTCH PPS standard Federal rate set forth under § 412.523(c)(3)(xvi) (that is, $42,677.64).

Table IV shows the estimated impact for LTCH PPS standard Federal payment rate cases. The estimated change attributable solely to the proposed annual update of 2.5 percent to the LTCH PPS standard Federal payment rate is projected to result in an increase of 2.5 percent in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2020 to FY 2021, on average, for all LTCHs (Column 6). The estimated increase of 2.5 percent shown in Column 6 of Table IV also includes estimated payments for short-stay outlier (SSO) cases, a portion of which are not affected by the annual update to the LTCH PPS standard Federal payment rate, as well as the reduction that is applied to the annual update for LTCHs that do not submit the required LTCH QRP data. However, for all hospital categories, the projected increase in payments based on the LTCH PPS standard Federal payment rate to LTCH PPS standard Federal payment rate cases still rounds to approximately 2.5 percent, the same as the proposed annual update for FY 2021.

For FY 2021, we are proposing to update the wage index values based on the most recent available data (data from cost reporting periods beginning during FY 2017 which is the same data used for the proposed FY 2021 IPPS wage index), the proposed labor-related share of 68.0 for FY 2021, based on the most recent available data (IGI's fourth quarter 2019 forecast) on the relative importance of the labor-related share of operating and capital costs of the proposed 2017-based LTCH market basket, and the proposed changes to the labor market areas based on the revisions to the CBSA delineations. We also are applying an area wage level budget neutrality factor of 1.0018755 to ensure that the proposed changes to the area wage level adjustment, including the proposed 5-percent cap transition policy, would not result in any change in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases.

We currently estimate total high cost outlier payments for LTCH PPS standard Federal payment rate cases will decrease from FY 2020 to FY 2021. Based on the FY 2019 LTCH cases that were used for the analyses in this proposed rule, we estimate that the FY 2020 high cost outlier threshold of $26,778 (as established in the FY 2020 IPPS/LTCH PPS final rule) would result in estimated high cost outlier payments for LTCH PPS standard Federal payment rate cases in FY 2020 that are projected to exceed the 7.975 percent target. Specifically, we currently estimate that high cost outlier payments for LTCH PPS standard Federal payment rate cases will be approximately 8.5 percent of the estimated total LTCH PPS standard Federal payment rate payments in FY 2020. Combined with our estimate that FY 2021 high cost outlier payments for LTCH PPS standard Federal payment rate cases will be 7.975 percent of estimated total LTCH PPS standard Federal payment rate payments in FY 2021, this will result in an estimated decrease in high cost outlier payments of approximately 0.5 percent between FY 2020 and FY 2021. We note that, consistent with past practice, in calculating these estimated high cost outlier payments, we increased estimated costs by an inflation factor of 5.4 percent (determined by the Office of the Actuary) to update the FY 2019 costs of each case to FY 2021.

Table IV shows the estimated impact of the payment rate and policy changes on LTCH PPS payments for LTCH PPS standard Federal payment rate cases for FY 2021 by comparing estimated FY 2020 LTCH PPS payments to estimated FY 2021 LTCH PPS payments. (As noted earlier, our analysis does not reflect changes in LTCH admissions or case-mix intensity.) We note that these impacts do not include LTCH PPS site neutral payment rate cases for the reasons discussed in section I.J.3. of this Appendix.

As we discuss in detail throughout this proposed rule, based on the most recent available data, we believe that the provisions of this proposed rule relating to the LTCH PPS, which are projected to result in an overall increase in estimated aggregate LTCH PPS payments, and the resulting LTCH PPS payment amounts will result in appropriate Medicare payments that are consistent with the statute.

2. Proposed Impact on Rural Hospitals

For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. As shown in Table IV, we are projecting a 1.8 percent increase in estimated payments for LTCH PPS standard Federal payment rate cases for LTCHs located in a rural area. This estimated impact is based on the FY 2019 data for the 17 rural LTCHs (out of 360 LTCHs) that were used for the impact analyses shown in Table IV.

3. Anticipated Effects of LTCH PPS Payment Rate Changes and Policy Changes

a. Proposed Budgetary Impact

Section 123(a)(1) of the BBRA requires that the PPS developed for LTCHs ''maintain budget neutrality.'' We believe that the statute's mandate for budget neutrality applies only to the first year of the

implementation of the LTCH PPS (that is, FY 2003). Therefore, in calculating the FY 2003 standard Federal payment rate under § 412.523(d)(2), we set total estimated payments for FY 2003 under the LTCH PPS so that estimated aggregate payments under the LTCH PPS were estimated to equal the amount that would have been paid if the LTCH PPS had not been implemented.

Section 1886(m)(6)(A) of the Act establishes a dual rate LTCH PPS payment structure with two distinct payment rates for LTCH discharges beginning in FY 2016. Under this statutory change, LTCH discharges that meet the patient-level criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid based on the LTCH PPS standard Federal payment rate. LTCH discharges paid at the site neutral payment rate are generally paid the lower of the IPPS comparable per diem amount, reduced by 4.6 percent for FYs 2018 through 2026, including any applicable HCO payments, or 100 percent of the estimated cost of the case, reduced by 4.6 percent. The statute also establishes a transitional payment method for cases that are paid at the site neutral payment rate for LTCH discharges occurring in cost reporting periods beginning during FY 2016 through FY 2019, under which the site neutral payment rate cases are paid based on a blended payment rate calculated as 50 percent of the applicable site neutral payment rate amount for the discharge and 50 percent of the applicable LTCH PPS standard Federal payment rate for the discharge.

As discussed in section I.J.2. of this Appendix, we project a decrease in aggregate LTCH PPS payments in FY 2021 of approximately $36 million. This estimated decrease in payments reflects the projected increase in payments to LTCH PPS standard Federal payment rate cases of approximately $69 million and the projected decrease in payments to site neutral payment rate cases of approximately $105 million under the dual rate LTCH PPS payment rate structure required by the statute beginning in FY 2016. (We note that these calculations are based on unrounded numbers and thus may not sum as expected.)

As discussed in section V.D. of the Addendum to this proposed rule, our actuaries project cost and resource changes for site neutral payment rate cases due to the site neutral payment rates required under the statute. Specifically, our actuaries project that the costs and resource use for cases paid at the site neutral payment rate will likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate, and will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG. While we are able to incorporate this projection at an aggregate level into our payment modeling, because the historical claims data that we are using in this proposed rule to project estimated FY 2021 LTCH PPS payments (that is, FY 2019 LTCH claims data) do not reflect this actuarial projection, we are unable to model the impact of the change in LTCH PPS payments for site neutral payment rate cases at the same level of detail with which we are able to model the impacts of the changes to LTCH PPS payments for LTCH PPS standard Federal payment rate cases. Therefore, Table IV only reflects changes in LTCH PPS payments for LTCH PPS standard Federal payment rate cases and, unless otherwise noted, the remaining discussion in section I.J.3. of this Appendix refers only to the impact on LTCH PPS payments for LTCH PPS standard Federal payment rate cases. In the following section, we present our proposed provider impact analysis for the changes that affect LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

b. Proposed Impact on Providers

The basic methodology for determining a per discharge payment for LTCH PPS standard Federal payment rate cases is currently set forth under §§ 412.515 through 412.533 and 412.535. In addition to adjusting the LTCH PPS standard Federal payment rate by the MS–LTC–DRG relative weight, we make adjustments to account for area wage levels and SSOs. LTCHs located in Alaska and Hawaii also have their payments adjusted by a COLA. Under our application of the dual rate LTCH PPS payment structure, the LTCH PPS standard Federal payment rate is generally only used to determine payments for LTCH PPS standard Federal payment rate cases (that is, those LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate). LTCH discharges that do not meet the patient-level criteria for exclusion are paid the site neutral payment rate, which we are calculating as the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), reduced by 4.6 percent for FYs 2018 through 2026, including any applicable outlier payments, or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). In addition, when certain thresholds are met, LTCHs also receive HCO payments for both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases that are paid at the IPPS comparable per diem amount.

To understand the impact of the changes to the LTCH PPS payments for LTCH PPS standard Federal payment rate cases presented in this proposed rule on different categories of LTCHs for FY 2021, it is necessary to estimate payments per discharge for FY 2020 using the rates, factors, and the policies established in the FY 2020 IPPS/LTCH PPS proposed rule and estimate payments per discharge for FY 2021 using the rates, factors, and the policies in this FY 2021 IPPS/LTCH PPS proposed rule (as discussed in section VII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule). As discussed elsewhere in this proposed rule, these estimates are based on the best available LTCH claims data and other factors, such as the application of inflation factors to estimate costs for HCO cases in each year. The resulting analyses can then be used to compare how our policies applicable to LTCH PPS standard Federal payment rate cases affect different groups of LTCHs.

For the following analysis, we group hospitals based on characteristics provided in the OSCAR data, cost report data in HCRIS, and PSF data. Hospital groups included the following:

- *Location:* Large urban/other urban/rural.
- Participation date.
- Ownership control.
- Census region.
- Bed size.

c. Proposed Calculation of LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases

For purposes of this impact analysis, to estimate the per discharge payment effects of our policies on payments for LTCH PPS standard Federal payment rate cases, we simulated FY 2020 and proposed FY 2021 payments on a case-by-case basis using historical LTCH claims from the FY 2019 MedPAR files that met or would have met the criteria to be paid at the LTCH PPS standard Federal payment rate if the statutory patient-level criteria had been in effect at the time of discharge for all cases in the FY 2019 MedPAR files. For modeling FY 2020 LTCH PPS payments, we used the FY 2020 standard Federal payment rate of $42,677.64 (or $41,844.90 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP). Similarly, for modeling payments based on the proposed FY 2021 LTCH PPS standard Federal payment rate, we used the proposed FY 2021 standard Federal payment rate of $43,849.28 (or $42,993.68 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP). In each case, we applied the applicable adjustments for area wage levels and the COLA for LTCHs located in Alaska and Hawaii. Specifically, for modeling FY 2020 LTCH PPS payments, we used the current FY 2020 labor-related share (66.3 percent), the wage index values established in the Tables 12A and 12B listed in the Addendum to the FY 2020 IPPS/LTCH PPS proposed rule (which are available via the internet on the CMS website), the FY 2020 HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases of $26,778 (as reflected in the FY 2020 IPPS/LTCH PPS final rule), and the FY 2020 COLA factors (shown in the table in section V.C. of the Addendum to that final rule) to adjust the FY 2020 nonlabor-related share (33.7 percent) for LTCHs located in Alaska and Hawaii. Similarly, for modeling FY 2021 LTCH PPS payments, we used the proposed FY 2021 LTCH PPS labor-related share (68.0 percent), the proposed FY 2021 wage index values from Tables 12A and 12B listed in section VI. of the Addendum to this proposed rule (which are available via the internet on the CMS website), the FY 2021 fixed-loss amount for LTCH PPS standard Federal payment rate cases of $30,515 (as discussed in section V.D.3. of the Addendum to this proposed rule), and the proposed FY 2021 COLA factors (shown in the table in section V.C. of the Addendum to this proposed rule) to adjust the FY 2021 nonlabor-related share (32.0 percent) for LTCHs located in Alaska and Hawaii. We note that in modeling payments for HCO cases for LTCH PPS standard Federal payment rate cases, we applied an inflation

factor of 2.5 percent (determined by the Office of the Actuary) to update the FY 2019 costs of each case to FY 2020, and an inflation factor of 5.4 percent (determined by the Office of the Actuary) to update the FY 2019 costs of each case to FY 2021.

The impacts that follow reflect the estimated ''losses'' or ''gains'' among the various classifications of LTCHs from FY 2020 to FY 2021 based on the payment rates and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this proposed rule. Table IV illustrates the estimated aggregate impact of the change in LTCH PPS payments for LTCH PPS standard Federal payment rate cases among various classifications of LTCHs. (As discussed previously, these impacts do not include LTCH PPS site neutral payment rate cases.)

- The first column, LTCH Classification, identifies the type of LTCH.
- The second column lists the number of LTCHs of each classification type.
- The third column identifies the number of LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria.
- The fourth column shows the estimated FY 2020 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The fifth column shows the estimated FY 2021 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The sixth column shows the percentage change in estimated payments per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria from FY 2020 to FY 2021 due to the proposed annual update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this proposed rule).
- The seventh column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2020 to FY 2021 for changes due to the proposed changes to the area wage level adjustment (that is, the updated hospital wage data, proposed labor-related share, and the proposed to the geographic labor-market area designations, including the proposed 5-percent cap transition policy), and the application of the proposed corresponding budget neutrality factor (as discussed in section V.B.6. of the Addendum to this proposed rule).
- The eighth column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2020 (Column 4) to FY 2021 (Column 5) for all proposed changes.

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TABLE IV: IMPACT OF PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR LTCH PPS STANDARD FEDERAL PAYMENT RATE CASES FOR FY 2021 (ESTIMATED FY 2020 PAYMENTS COMPARED TO ESTIMATED PROPOSED FY 2021 PAYMENTS)

LTCH Classification (1)	No. of LTCHS (2)	Number of LTCH PPS Standard Payment Rate Cases (3)	Average FY 2020 LTCH PPS Payment Per Standard Payment Rate (4)	Average FY 2021 LTCH PPS Payment Per Standard Payment Rate[1] (5)	Change Due to Change to the Proposed Annual Update to the Standard Federal Rate[2] (6)	Percent Change Due to Proposed Changes to Area Wage Adjustment with Wage Budget Neutrality[3] (7)	Percent Change Due to All Proposed Standard Payment Rate Changes[4] (8)
ALL PROVIDERS	360	68,473	48,298	49,303	2.5	0.1	2.1
BY LOCATION:							
RURAL	17	2,592	38,311	39,016	2.6	-0.1	1.8
URBAN	343	65,881	48,690	49,708	2.5	0.1	2.1
BY PARTICIPATION DATE:							
BEFORE OCT. 1983	10	1,773	45,187	46,062	2.5	-0.2	1.9
OCT. 1983 - SEPT. 1993	40	8,845	53,994	55,168	2.4	0.3	2.2
OCT. 1993 - SEPT. 2002	145	28,085	47,297	48,257	2.5	0.0	2.0
AFTER OCTOBER 2002	165	29,770	47,734	48,740	2.5	0.1	2.1
BY OWNERSHIP TYPE:							
VOLUNTARY	60	8,466	50,624	51,665	2.5	0.0	2.1
PROPRIETARY	290	58,861	47,711	48,708	2.5	0.1	2.1
GOVERNMENT	10	1,146	61,257	62,432	2.3	0.1	1.9
BY REGION:							
NEW ENGLAND	10	2,363	43,298	44,086	2.5	-0.5	1.8
MIDDLE ATLANTIC	23	5,296	56,409	57,453	2.5	-0.3	1.9
SOUTH ATLANTIC	62	13,038	47,728	48,684	2.5	0.1	2.0
EAST NORTH CENTRAL	55	10,199	47,345	48,267	2.5	0.0	2.0
EAST SOUTH CENTRAL	31	5,757	43,810	44,610	2.5	-0.2	1.8

LTCH Classification (1)	No. of LTCHS (2)	Number of LTCH PPS Standard Payment Rate Cases (3)	Average FY 2020 LTCH PPS Payment Per Standard Payment Rate (4)	Average FY 2021 LTCH PPS Payment Per Standard Payment Rate[1] (5)	Change Due to Change to the Proposed Annual Update to the Standard Federal Rate[2] (6)	Percent Change Due to Proposed Changes to Area Wage Adjustment with Wage Budget Neutrality[3] (7)	Percent Change Due to All Proposed Standard Payment Rate Changes[4] (8)
WEST NORTH CENTRAL	22	4,139	45,847	46,622	2.5	-0.3	1.7
WEST SOUTH CENTRAL	105	17,145	43,260	44,216	2.5	0.2	2.2
MOUNTAIN	29	3,354	49,781	50,782	2.5	-0.2	2.0
PACIFIC	23	7,182	62,689	64,364	2.3	0.7	2.7
BY BED SIZE:							
BEDS: 0-24	25	2,724	46,112	46,921	2.5	-0.5	1.8
BEDS: 25-49	165	23,454	45,156	46,090	2.5	0.0	2.1
BEDS: 50-74	98	19,121	48,647	49,711	2.5	0.2	2.2
BEDS: 75-124	45	13,290	52,945	54,033	2.4	0.1	2.1
BEDS: 125-199	19	5,946	50,290	51,288	2.5	0.1	2.0
BEDS: 200+	8	3,938	48,131	49,145	2.5	0.2	2.1

[1] Estimated FY 2021 LTCH PPS payments for LTCH PPS standard Federal payment rate criteria based on the payment rate and factor changes applicable to such cases presented in the preamble of and the Addendum to this proposed rule.

[2] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2020 to FY 2021 for the proposed annual update to the LTCH PPS standard Federal payment rate.

[3] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2020 to FY 2021 for changes due to the proposed changes to the area wage level adjustment under § 412.525(c) (i.e., updated hospital wage data, the proposed labor related share, the proposed to the geographic labor-market area designations, and the 5-percent cap transition, as discussed in section V.B. of the Addendum to this proposed rule).

[4] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2020 (shown in Column 4) to FY 2021 (shown in Column 5), including all of the changes to the rates and factors applicable to such cases presented in the preamble and the Addendum to this proposed rule. We note that this column, which shows the percent change in estimated payments per discharge for all changes, does not equal the sum of the percent changes in estimated payments per discharge for the annual update to the LTCH PPS standard Federal payment rate (Column 6) and the changes due to the proposed changes to the area wage level adjustment with budget neutrality (Column 7) due to the effect of estimated changes in estimated payments to aggregate HCO payments for LTCH PPS standard Federal payment rate cases (as discussed in this impact analysis), as well as other interactive effects that cannot be isolated.

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d. Results

Based on the FY 2019 LTCH cases (from 360 LTCHs) that were used for the analyses in this proposed rule, we have prepared the following summary of the impact (as shown in Table IV) of the LTCH PPS payment rate and proposed policy changes for LTCH PPS standard Federal payment rate cases presented in this proposed rule. The impact analysis in Table IV shows that estimated payments per discharge for LTCH PPS

standard Federal payment rate cases are projected to increase 2.1 percent, on average, for all LTCHs from FY 2020 to FY 2021 as a result of the payment rate and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this proposed rule. This estimated 2.1 percent increase in LTCH PPS payments per discharge was determined by comparing estimated FY 2021 LTCH PPS payments (using the proposed payment rates and factors discussed in this proposed rule) to estimated FY 2020 LTCH PPS payments for LTCH discharges which will be LTCH PPS standard Federal payment rate cases if the dual rate LTCH PPS payment structure was or had been in effect at the time of the discharge (as described in section I.J.3. of this Appendix).

As stated previously, we are proposing to update the LTCH PPS standard Federal payment rate for FY 2021 by 2.5 percent. For LTCHs that fail to submit quality data under the requirements of the LTCH QRP, as required by section 1886(m)(5)(C) of the Act, a 2.0 percentage point reduction is applied to the annual update to the LTCH PPS standard Federal payment rate. In addition, we are applying the incremental change in the one-time budget neutrality adjustment factor of 0.991249 for the cost of eliminating the 25-percent threshold policy in FY 2021 as discussed in section VII.D. of the preamble of this proposed rule. Consistent with § 412.523(d)(4), we also are applying a proposed budget neutrality factor for proposed changes to the area wage level adjustment of 1.0018755 (discussed in section V.B.6. of the Addendum to this proposed rule), based on the best available data at this time, to ensure that any proposed changes to the area wage level adjustment will not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. As we also explained earlier in this section, for most categories of LTCHs (as shown in Table IV, Column 6), the estimated payment increase due to the proposed 2.5 percent annual update to the LTCH PPS standard Federal payment rate is projected to result in approximately a 2.5 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases for all LTCHs from FY 2020 to FY 2021. We note our estimate of the changes in payments due to the update to the LTCH PPS standard Federal payment rate also reflects estimated payments for SSO cases that are paid using a methodology that is not entirely affected by the update to the LTCH PPS standard Federal payment rate. Consequently, for certain hospital categories, we estimate that payments to LTCH PPS standard Federal payment rate cases may increase by slightly less than 2.5 percent due to the annual update to the LTCH PPS standard Federal payment rate for FY 2021.

(1) Location

Based on the most recent available data, the vast majority of LTCHs are located in urban areas. Only approximately 5 percent of the LTCHs are identified as being located in a rural area, and approximately 4 percent of all LTCH PPS standard Federal payment rate cases are expected to be treated in these rural hospitals. The impact analysis presented in Table IV shows that the overall average percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2020 to FY 2021 for all hospitals is 2.1 percent. The projected increase for urban hospitals is 2.1 percent for urban hospitals, while the projected increase for rural hospitals is 1.8 percent. This smaller than average projected increase for rural LTCHs is primarily due to the proposed changes to the area wage adjustment, including the proposed changes to the labor market areas.

(2) Participation Date

LTCHs are grouped by participation date into four categories: (1) Before October 1983; (2) between October 1983 and September 1993; (3) between October 1993 and September 2002; and (4) October 2002 and after. Based on the most recent available data, the categories of LTCHs with the largest expected percentage of LTCH PPS standard Federal payment rate cases (approximately 41 percent and 43 percent, respectively) are in LTCHs that began participating in the Medicare program between October 1993 and September 2002 and after October 2002. These LTCHs are expected to experience an increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2020 to FY 2021 of 2.0 percent and 2.1 percent, respectively. LTCHs that began participating in the Medicare program between October 1983 and September 1993 are projected to experience the largest percent increase, 2.2 percent, in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2020 to FY 2021, as shown in Table IV.

Approximately 3 percent of LTCHs began participating in the Medicare program before October 1983, and these LTCHs are projected to experience an average percent increase of 1.9 percent in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2020 to FY 2021. Approximately 40 percent of LTCHs began participating in the Medicare program between October 1993 and September 2002, and these LTCHs are projected to experience an increase of 2.0 percent in estimated payments for LTCH PPS standard Federal payment rate cases from FY 2020 to FY 2021. LTCHs that began participating in the Medicare program after October 1, 2002, which treat approximately 43 percent of all LTCH PPS standard Federal payment rate cases, are projected to experience a 2.1 percent increase in estimated payments from FY 2020 to FY 2021.

(3) Ownership Control

LTCHs are grouped into three categories based on ownership control type: Voluntary, proprietary, and government. Based on the most recent available data, approximately 17 percent of LTCHs are identified as voluntary (Table IV). The majority (approximately 80 percent) of LTCHs are identified as proprietary, while government owned and operated LTCHs represent approximately 3 percent of LTCHs. Based on ownership type, voluntary and proprietary LTCHs are each expected to experience a 2.1 percent increase in payments to LTCH PPS standard Federal payment rate cases. Government owned and operated LTCHs, meanwhile, are expected to experience a 1.9 percent increase in payments to LTCH PPS standard Federal payment rate cases from FY 2020 to FY 2021.

(4) Census Region

Estimated payments per discharge for LTCH PPS standard Federal payment rate cases for FY 2021 are projected to increase across all census regions. LTCHs located in the Pacific region are projected to experience the largest increase at 2.7 percent. The remaining regions are projected to experience an increase in payments in the range of 1.7 to 2.2 percent. These regional variations are primarily due to the proposed changes to the area wage adjustment, including the proposed changes to the labor market areas.

(5) Bed Size

LTCHs are grouped into six categories based on bed size: 0–24 beds; 25–49 beds; 50–74 beds; 75–124 beds; 125–199 beds; and greater than 200 beds. We project that LTCHs with 0–24 beds will experience the lowest increase in payments for LTCH PPS standard Federal payment rate cases, 1.8 percent. The majority of LTCHs, that is those with 25–49 beds, 75–124 beds, and with 200 or more beds, will experience an increase in payments for LTCH PPS standard Federal payment rate cases of 2.1 percent. LTCHs with 50–74 beds are projected to experience the largest increase in payments of 2.2 percent.

5. Effect on the Medicare Program

As stated previously, we project that the provisions of this proposed rule will result in an increase in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases in FY 2021 relative to FY 2020 of approximately $69 million (or approximately 2.1 percent) for the 360 LTCHs in our database. Although, as stated previously, the hospital-level impacts do not include LTCH PPS site neutral payment rate cases, we estimate that the provisions of this proposed rule will result in a decrease in estimated aggregate LTCH PPS payments to site neutral payment rate cases in FY 2021 relative to FY 2020 of approximately $105 million (or approximately −21 percent) for the 360 LTCHs in our database. (As noted previously, we estimate payments to site neutral payment rate cases in FY 2021 represent approximately 10 percent of total estimated FY 2021 LTCH PPS payments.) Therefore, we project that the provisions of this proposed rule will result in a decrease in estimated aggregate LTCH PPS payments for all LTCH cases in FY 2021 relative to FY 2020 of approximately $36 million (or approximately −0.9 percent) for the 360 LTCHs in our database.

6. Effect on Medicare Beneficiaries

Under the LTCH PPS, hospitals receive payment based on the average resources consumed by patients for each diagnosis. We do not expect any changes in the quality of care or access to services for Medicare beneficiaries as a result of this proposed rule, but we continue to expect that paying prospectively for LTCH services will enhance the efficiency of the Medicare program. As discussed previously, we do not expect the

continued implementation of the site neutral payment system to have a negative impact on access to or quality of care, as demonstrated in areas where there is little or no LTCH presence, general short-term acute care hospitals are effectively providing treatment for the same types of patients that are treated in LTCHs.

K. Effects of Proposed Requirements for the Hospital Inpatient Quality Reporting (IQR) Program

In section VIII.A. of the preamble of this proposed rule, we discuss our proposed requirements for hospitals to report quality data under the Hospital IQR Program in order to receive the full annual percentage increase for the FY 2022 payment determination and subsequent years.

In this proposed rule, we are proposing reporting, submission, and public display requirements for eCQMs, including policies to: (1) Progressively increase the numbers of quarters of eCQM data reported, from one self-selected quarter of data to four quarters of data over a 3-year period, by requiring hospitals to report: (a) Two quarters of data for the CY 2021 reporting period/FY 2023 payment determination for each of the four self-selected eCQMs; (b) three quarters of data for the CY 2022 reporting period/FY 2024 payment determination for three self-selected eCQMS and the Safe Use of Opioids eCQM; and (c) four quarters of data beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years, while continuing to allow hospitals to report: (i) Three self-selected eCQMs, and (ii) the Safe Use of Opioids eCQM; and (2) begin public display of eCQM data beginning with data reported by hospitals for the CY 2021 reporting period and for subsequent years. The Hospital IQR Program eCQM-related proposals are in alignment with proposals under the Promoting Interoperability Program. We also are proposing to expand the requirement to use EHR technology certified to the 2015 Edition for submitting data on not only the previously finalized Hybrid Hospital-Wide Readmission measure, but all hybrid measures in the Hospital IQR Program. While we believe there would be no change to the information collection burden estimate due to public display of eCQM data, we acknowledge that there is other burden associated with this proposal. For example, there is burden associated with the optional reviewing of hospital-specific reports during the public reporting preview; however, we believe this burden is nominal because hospitals already review these reports with respect to other types of measures for the Hospital IQR Program.

We also are proposing to make several changes to streamline validation processes under the Hospital IQR Program. We are proposing to: (1) Require the use of electronic file submissions via a CMS-approved secure file transmission process and no longer allow the submission of paper copies of medical records or copies on digital portable media such as CD, DVD, or flash drive starting with validation affecting the FY 2024 payment determination; (2) combine the validation processes for chart-abstracted measures and eCQMs for validation affecting the FY 2024 payment determination by: (a) Aligning data submission quarters; (b) combining hospital selection, including: (i) Reducing the pool of hospitals randomly selected for chart-abstracted measure validation; and (ii) integrating and applying targeting criteria for eCQM validation; (c) removing previous exclusion criteria; and (d) combining scoring processes by providing one combined validation score for the validation of chart-abstracted measures and eCQMs with the eCQM portion of the combined score weighted at zero; and (3) formalize the process for conducting educational reviews for eCQM validation affecting the FY 2023 payment determination in alignment with current processes for providing feedback for chart-abstracted validation results.

We estimate a total information collection burden increase for 3,300 IPPS hospitals of 6,533 hours (6,600 hours − 67 hours) associated with our proposed policies and updated burden estimates and a total cost increase related to this information collection of approximately $253,480 ($38.80 hourly wage × 6,533 hours) (which also reflects use of an updated hourly wage rate), across a 4-year period from the CY 2021 reporting period/FY 2023 payment determination through the CY 2024 reporting period/FY 2026 payment determination, compared to our currently approved information collection burden estimates. We refer readers to section XI.B.7. 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 IQR Program.

With regard to our proposal to combine the hospital selection process, including the reduction of the pool of hospitals randomly selected for chart-abstracted measure validation from 400 hospitals to up to 200 hospitals, while we expect no change to the information collection burden for the Hospital IQR Program as discussed in section XI.B.7.b. of this preamble of this proposed rule because we directly reimburse hospitals for medical records, we believe there may be other cost savings beyond information collection burden due to 200 fewer hospitals being selected for Hospital IQR Program validation each year.

Historically, 100 hospitals, on average, that participate in the Hospital IQR Program do not receive the full annual percentage increase in any fiscal year due to the failure to meet all requirements of this Program. We anticipate that the number of hospitals not receiving the full annual percentage increase will be approximately the same as in past years.

L. Effects of Requirements for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

In section VIII.B. of the preamble of this proposed rule, we discuss our proposed policies for the quality data reporting program for PPS-exempt cancer hospitals (PCHs), which we refer to as the PPS-exempt Cancer Hospital Quality Reporting (PCHQR) Program. The PCHQR Program is authorized under section 1866(k) of the Act, which was added by section 3005 of the Affordable Care Act. There is no financial impact to PCH Medicare reimbursement if a PCH does not submit data.

In section VIII.B.4. of the preamble of this proposed rule, we are proposing to adopt refined versions of two existing measures: The Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure and the Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure, beginning with the FY 2023 program year. As explained in section XI.B.8. of the preamble of this proposed rule, we do not anticipate any change in burden hours on the PCHs associated with our proposal to refine the CAUTI and CLABSI measures beginning with the FY 2023 program year because there are no changes to the data submission requirements for CAUTI and CLABSI.

M. Effects of Proposed Requirements for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

We are not proposing any new policies for the LTCH QRP in this proposed rule.

N. Effects of Proposed Requirements Regarding the Promoting Interoperability Programs

In section VIII.D. of the preamble of this proposed rule, we discuss our proposed requirements for eligible hospitals and CAHs participating in the Medicare and Medicaid Promoting Interoperability Programs. Specifically, we are proposing the following changes for eligible hospitals and CAHs that attest to CMS under the Medicare Promoting Interoperability Program: (1) An EHR reporting period of a minimum of any continuous 90-day period in CY 2022 for new and returning participants (eligible hospitals and CAHs); (2) to maintain the Electronic Prescribing Objective's Query of PDMP measure as optional and worth 5 bonus points in CY 2021; (3) to modify the name of the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure; (4) to progressively increase the number of quarters for which hospitals are required to report eCQM data, from the current requirement of one self-selected calendar quarter of data, to four calendar quarters of data, over a three year period. Specifically, we propose to require: (a) 2 self-selected calendar quarters of data for the CY 2021 reporting period; (b) 3 self-selected calendar quarters of data for the CY 2022 reporting period; and (c) 4 self-selected calendar quarters of data beginning with the CY 2023 reporting period, where the proposed submission period for the Medicare Promoting Interoperability Program would be the 2 months following the close of the CY 2023 (ending February 28, 2024); (5) to begin publicly reporting eCQM performance data beginning with the eCQM data reported by eligible hospitals and CAHs for the reporting period in CY 2021 on the *Hospital Compare* and/or *data.medicare.gov* websites or successor websites; (6) to correct errors and amend regulation text under § 495.104(c)(5)(viii)(B) through (D) regarding transition factors under section 1886(n)(2)(E)(i) for the incentive payments for Puerto Rico eligible hospitals; and (7) to correct errors and amend regulation text

under § 495.20(e)(5)(iii) and (l)(11)(ii)(C)(*1*) for regulatory citations for the ONC certification criteria. We are amending our regulation texts as necessary to incorporate these proposed changes. For the EHR reporting period in CY 2021, the proposals summarized here are mainly continuations of existing policies. However, two updated instances of a previous miscalculation and an updated Bureau of Labor Statistics wage rate will result in both a minor reduction of program burden hours (−44) as well as a small increase in total cost (+$24,024) for CY 2021.

O. Alternatives Considered

This proposed rule contains a range of policies. It also provides descriptions of the statutory provisions that are addressed, identifies the proposed policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

1. Proposed Implementation of Revised Labor Market Area Delineations

As discussed in section III.A.2. of the preamble of this proposed rule, the wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs). 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. On September 14, 2018, OMB issued OMB Bulletin No. 18–04. While OMB Bulletin No. 18–04 is not based on new census data, it includes some material changes to the OMB statistical area delineations. Specifically, under the revised OMB delineations, there would be some new CBSAs, urban counties that would become rural, rural counties that would become urban, and existing CBSAs would be split apart. In addition, the revised OMB delineations would affect various hospital reclassifications, the out-migration adjustment (established by section 505 of Public Law 108–173), and treatment of hospitals located in certain rural counties (that is, ''Lugar'' hospitals) under section 1886(d)(8)(B) of the Act.

We considered whether we should propose to implement the revised OMB delineations as described in OMB Bulletin No. 18–04, beginning with the FY 2021 IPPS wage index, or whether we should wait to propose to implement any further changes to the hospital labor market areas until OMB issues revisions to the statistical areas based on the results of the upcoming decennial census. We believe it is important for the IPPS to use the latest labor market area delineations as soon as reasonably possible in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. Furthermore, we believe that using the most current delineations will increase the integrity of the IPPS wage index system by creating a more accurate representation of geographic variations in wage levels. Therefore, we decided not to wait until OMB issues revisions to the statistical areas based on the results of the upcoming decennial census, but are proposing to implement the revised OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, effective October 1, 2020 beginning with the FY 2021 IPPS wage index. We note that as described in section III.A.2.c. of the preamble of this proposed rule, we are proposing a transition for hospitals that would see a decrease of more than 5 percent in their FY 2021 wage index compared to their FY 2020 wage index.

2. Market-Based MS–DRG Relative Weight Estimation Data Collection and Potential Change in Methodology for Calculating MS–DRG Relative Weights

In section IV.P.2.c. of the preamble of this proposed rule, we are proposing that hospitals would report on the Medicare cost report: (1) The median payer-specific negotiated charge that the hospital has negotiated with all of its Medicare Advantage (MA) organizations (also referred to as MA organizations) payers, by MS–DRG; and (2) the median payer-specific negotiated charge the hospital has negotiated with all of its third-party payers, which would include MA organizations, by MS–DRG. The market-based rate information we are proposing to collect on the Medicare cost report would be the median of the payer-specific negotiated charges by MS–DRG, as described previously, for a hospital's MA organization payers and all of its third party payers. The payer-specific negotiated charges used by hospitals to calculate these medians would be the payer-specific negotiated charges for service packages that hospitals are required to make public under the requirements we finalized in the Hospital Price Transparency final rule (84 FR 65524) that can be cross-walked to an MS–DRG. We note that we may also consider finalizing the collection of alternative market-based data, such as the median negotiated reimbursement amount as explained in section IV.P.2.c. of this proposed rule, or any refinements to the definition of median payer-specific negotiated charge, based on review of public comments. We are also considering a modification to the market based data collection proposal, to require only the reporting of the median payer-specific negotiated charge for MA organizations on the Medicare cost report. We are inviting public comments on our proposed data collection, as well as on these or other alternative data collections of payer-specific negotiated charges or other market-based information on the Medicare cost report, which we may consider finalizing in the FY 2021 IPPS/LTCH PPS final rule for cost reporting periods ending on or after January 1, 2021, after consideration of the comments received.

In section IV.P.2.d. of the preamble of this proposed rule, we are requesting comments on a potential new market-based methodology for estimating the MS–DRG relative weights, beginning in FY 2024, and which we may consider adopting in the FY 2021 IPPS/LTCH PPS final rule. This potential new market-based methodology would be based on the proposed median payer-specific negotiated charge information collected on the Medicare cost report. In this methodology, we are also considering alternatives to this approach, such as the use of the median payer-specific negotiated charge for all third-party payers (instead of the median payer-specific negotiated charge for all MA organizations), or other alternative collections of payer-specific negotiated charges or other market-based information such as a median negotiated reimbursement amount that a hospital negotiates with its MA organizations or third party payers (as described further in section IV.P.2.c of the preamble of this proposed rule), within the MS–DRG relative weight methodology.

The same relative weight calculation described in section IV.P.2.d. would be used if an alternative to the median payer-specific negotiated charge was collected on the Medicare cost report, as further described in that section. We are requesting comments on this potential new market-based methodology for estimating the MS–DRG relative weights beginning in FY 2024, including comments on any suggested refinements to this potential methodology or alternative approaches, which we may consider adopting in the FY 2021 IPPS/LTCH final rule. Within Step Two of the potential MS–DRG relative weight methodology described in section IV.P.2.d. of the preamble of this proposed rule, we note that we are considering alternative weighting factors such as using the unadjusted Medicare case counts, or other alternative approaches based on the review of public comments. In Step Three of the potential methodology we also reference that if an alternative weighting factor to the Medicare transfer adjusted case counts was used in Step Two we would use that same alternative weight factor in Step Three.

If we were to finalize a change in the IPPS FY 2021 rulemaking to incorporate payer-specific negotiated charges within the MS–DRG relative weight methodology, effective for FY 2024, we are open to adjusting any finalized policy, through future rulemaking, prior to the FY 2024 effective date. Should we finalize our data collection proposal, we would conduct further analysis based on the data received and provide an opportunity for public comment on that analysis, prior to the FY 2024 effective date.

P. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. This proposed rule is considered to be an E.O. 13771 regulatory action. We estimate that this rule generates approximately $2.4 million in annualized costs, discounted at 7 percent relative to fiscal year 2016, over a perpetual time horizon.

We discuss the estimated burden and costs for the Hospital IQR Program in section XI.B.7. of the preamble of this proposed rule, and estimate that the impact of these changes is an increase in costs of approximately $253,480 (which also reflects use of an updated hourly wage rate), across a 4-year period from the CY 2021 reporting period/FY

2023 payment determination through the CY 2024 reporting period/FY 2026 payment determination, or $77 per hospital across the 4-year period.

We discuss the estimated burden and costs for the PCHQR Program in section XI.B.8. of the preamble of this proposed rule, and estimate that the impact of these changes is an increase in costs of approximately $86,388 across all PPS-exempt cancer hospitals. This estimate reflects an updated hourly wage. There are no estimated changes to the estimated number of burden hours under the program.

We do not anticipate an increase or decrease in burden and costs for the Long-Term Care Hospital Quality Reporting Program as there are no new proposed policies in this proposed rule.

We discuss the estimated burden for the Hospital-Acquired Condition Reduction Program in section XI.B.6. of the preamble of this proposed rule and estimate the impact of these changes is a decrease in costs of approximately −$558,720 (which also reflects use of an updated hourly wage rate) across all subsection (d) hospitals annually.

We do not anticipate an increase or decrease in burden and costs for the Hospital Readmissions Reduction Program or the Hospital Value-Based Purchasing Program based on the proposed policies in this proposed rule.

Also, as noted in section I.R. of this Appendix, the regulatory review cost for this proposed rule is $16,090,234. Section I.H.11. of this Appendix discusses annual savings of $14.4 million, but this amount has not yet been incorporated into E.O. 13771 accounting, pending the estimation of associated transition costs.

Section of the Proposed Rule	Description	Amount of Costs or Savings
Section XI.B.7. of the preamble	ICRs for the Hospital IQR Program	$253,480
Section XI.B.8. of the preamble	ICRs for the PCHQR Program	$86,388
Section XI.B.6. of the preamble	ICRs for the HAC Reduction Program	-$558,720
	Total	-$218,852

Q. Overall Conclusion

1. Acute Care Hospitals

Acute care hospitals are estimated to experience an increase of approximately $2.067 billion in FY 2021, including operating, capital, and new technology changes as modeled for this proposed rule. The estimated change in operating payments is approximately $1.978 billion (discussed in section I.G. and I.H. of this Appendix). The estimated change in capital payments is approximately $0.036 billion (discussed in section I.I. of this Appendix). The estimated change in new technology add-on payments is approximately $0.053 billion as discussed in section I.H. of this Appendix. The change in new technology add-on payments reflects the net impact of continuing and expiring current new technology add on payments. Total may differ from the sum of the components due to rounding.

Table I. of section I.G. of this Appendix also demonstrates the estimated redistributional impacts of the IPPS budget neutrality requirements for the proposed MS–DRG and wage index changes, and for the wage index reclassifications under the MGCRB.

We estimate that hospitals would experience a 0.4 percent increase in capital payments per case, as shown in Table III. of section I.I. of this Appendix. We project that there would be a $36 million increase in capital payments in FY 2021 compared to FY 2020.

The discussions presented in the previous pages, in combination with the remainder of this proposed rule, constitute a regulatory impact analysis.

2. LTCHs

Overall, LTCHs are projected to experience an increase in estimated payments per discharge in FY 2021. In the impact analysis, we are using the proposed rates, factors, and policies presented in this proposed rule based on the best available claims and CCR data to estimate the change in payments under the LTCH PPS for FY 2021. Accordingly, based on the best available data for the 360 LTCHs in our database, we estimate that overall FY 2021 LTCH PPS payments will decrease approximately $36 million relative to FY 2020 primarily as a result of the end of the statutory transition period for site neutral payment rate cases.

R. 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 would review the proposed rule, we assumed that the total number of timely pieces of correspondence on last year's proposed rule would be the number of reviewers of the proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing the 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 those reasons, and consistent with our approach in previous rulemakings (83 FR 41777 and 84 FR 42697), we believe that the number of past commenters would be a fair estimate of the number of reviewers of the proposed rule. We welcome any public comments on the approach in estimating the number of entities that will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of the proposed rule. Therefore, for the purposes of our estimate, and consistent with our approach in previous rulemaking (83 FR 41777 and 84 FR 42697), we assume that each reviewer read approximately 50 percent of the proposed rule. We welcome public comments on this assumption.

We have used the number of timely pieces of correspondence on the FY 2020 proposed rule as our estimate for the number of reviewers of this proposed rule. We continue to acknowledge the uncertainty involved with using this number, but we believe it is a fair estimate due to the variety of entities affected and the likelihood that some of them choose to rely (in full or in part) on press releases, newsletters, fact sheets, or other sources rather than the comprehensive review of preamble and regulatory text. Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing the proposed rule is $109.36 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 18.76 hours for the staff to review half of this proposed rule. For each IPPS hospital or LTCH that reviews this proposed rule, the estimated cost is $2,051 (18.76 hours × $109.36). Therefore, we estimate that the total cost of reviewing this proposed rule is $16,090,234 ($2,051 × 7,844 reviewers).

II. Accounting Statements and Tables

A. Acute Care Hospitals

As required by OMB Circular A–4 (available at *https://obamawhitehouse.archives.gov/omb/circulars_a-004_a-4/* and *https://georgewbush-whitehouse.archives.gov/omb/circulars/a004/a-4.html*), in Table V. of this Appendix, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate to acute care hospitals. This table provides our best estimate of the change in Medicare payments to providers as a result of the proposed changes to the IPPS presented in this proposed rule. All expenditures are classified as transfers to Medicare providers.

As shown in Table V. of this Appendix, the net costs to the Federal Government associated with the proposed policies in this proposed rule are estimated at $2.067 billion.

TABLE V.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2020 TO FY 2021

Category	Transfers
Annualized Monetized Transfers	$2.067 billion
From Whom to Whom	Federal Government to IPPS Medicare Providers

B. LTCHs

As discussed in section I.J. of this Appendix, the impact analysis of the proposed payment rates and factors presented in this proposed rule under the LTCH PPS is projected to result in a decrease in estimated aggregate LTCH PPS payments in FY 2021 relative to FY 2020 of approximately $36 million based on the data for 360 LTCHs in our database that are subject to payment under the LTCH PPS. Therefore, as required by OMB Circular A–4 (available at: *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/* and *https://georgewbush-whitehouse.archives.gov/omb/circulars/a004/a-4.html*), in Table VI. of this Appendix, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate to the changes to the LTCH PPS. Table VI. of this Appendix provides our best estimate of the estimated change in Medicare payments under the LTCH PPS as a result of the proposed payment rates and factors and other provisions presented in this proposed rule based on the data for the 360 LTCHs in our database. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

As shown in Table VI. of this Appendix, the net cost to the Federal Government associated with the policies for LTCHs in this proposed rule are estimated at −$36 million.

TABLE VI.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM THE FY 2020 LTCH PPS TO THE FY 2021 LTCH PPS

Category	Transfers
Annualized Monetized Transfers	$36 million
From Whom to Whom	LTCH Medicare Providers to Federal Government

III. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $7.5 million to $38.5 million in any 1 year). (For details on the latest standards for health care providers, we refer readers to page 36 of the Table of Small Business Size Standards for NAIC 622 found on the SBA website at: *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.*)

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity. We believe that the provisions of this proposed rule relating to acute care hospitals will have a significant impact on small entities as explained in this Appendix. For example, because all hospitals are considered to be small entities for purposes of the RFA, the hospital impacts described in this proposed rule are impacts on small entities. For example, we refer readers to ''Table I.—Impact Analysis of Proposed Changes to the IPPS for Operating Costs for FY 2021.'' Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary LTCHs. Therefore, we are assuming that all LTCHs are considered small entities for the purpose of the analysis in section I.J. of this Appendix. MACs are not considered to be small entities because they do not meet the SBA definition of a small business. Because we acknowledge that many of the affected entities are small entities, the analysis discussed throughout the preamble of this proposed rule constitutes our regulatory flexibility analysis. This proposed rule contains a range of proposed policies. It provides descriptions of the statutory provisions that are addressed, identifies the proposed policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

For purposes of the RFA, as stated previously, all hospitals and other providers and suppliers are considered to be small entities. We estimate the provisions of this proposed rule would result in an estimated $1.98 billion increase in FY 2021 payments to IPPS hospitals, primarily driven by the proposed applicable percentage increase to the IPPS rates in conjunction with other proposed payment changes including uncompensated care payments, capital payments, new technology add-on payments, and low-volume hospital payments, as discussed in section I.B. of this Appendix. As discussed in section I.J. of this Appendix, the impact analysis of the proposed payment rates and factors presented in this proposed rule under the LTCH PPS is projected to result in a decrease in estimated aggregate LTCH PPS payments in FY 2021 relative to FY 2020 of approximately $36 million. We are soliciting public comments on our estimates and analysis of the impact of our proposals on those small entities. Any public comments that we received and our responses will be presented throughout the final rule.

IV. Impact on Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any proposed or final rule that 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. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals. (As shown in Table I. in section I.G. of this Appendix, rural IPPS hospitals with 0–49 beds and 50–99 beds are expected to experience an increase in payments from FY 2020 to FY 2021 of 2.0 percent and 2.3 percent, respectively. We refer readers to Table I. in section I.G. of this Appendix for additional information on the quantitative effects of the proposed policy changes under the IPPS for operating costs.)

V. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) 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 2020, that threshold level is approximately $156 million. This proposed rule would not mandate any requirements for State, local, or tribal governments, nor would it affect private sector costs.

VI. Executive Order 13175

Executive Order 13175 directs agencies to consult with Tribal officials prior to the formal promulgation of regulations having tribal implications. Section 1880(a) of the Act states that a hospital of the Indian Health Service, whether operated by such Service or by an Indian tribe or tribal organization, is eligible for Medicare payments so long as it meets all of the conditions and requirements for such payments which are applicable generally to hospitals. Consistent with section 1880(a) of the Act, this proposed rule contains general provisions also applicable to hospitals and facilities operated by the Indian Health Service or Tribes or Tribal organizations under the Indian Self-Determination and Education Assistance Act.

As discussed in section IV.G.4. of the preamble of this proposed rule, we are seeking comment on a potential restructuring of Medicare DSH and uncompensated care payments for IHS and Tribal hospitals beginning in FY 2022. Consistent with Executive Order 13175, we have engaged in initial consultation with Tribal officials on this issue. We intend to consider input received from further consultation with Tribal officials, as well as the comments on this proposed rule on this issue, and may revisit our policies for FY 2022 either in the final rule or through future rulemaking.

VII. Executive Order 12866

In accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget reviewed this proposed rule.

Appendix B: Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services

I. Background

Section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Under section 1886(e)(5) of the Act, we are required to publish update factors recommended by the Secretary in the proposed and final IPPS rules. Accordingly, this Appendix provides the recommendations for the update factors for the IPPS national standardized amount, the hospital-specific rate for SCHs and MDHs, and the rate-of-increase limits for certain hospitals excluded from the IPPS, as well as LTCHs. In prior years, we made a recommendation in the IPPS proposed rule and final rule for the update factors for the payment rates for IRFs and IPFs. However, for FY 2021, consistent with our approach for FY 2020, we are including the Secretary's recommendation for the update factors for IRFs and IPFs in separate **Federal Register** documents at the time that we announce the annual updates for IRFs and IPFs. We also discuss our response to MedPAC's recommended update factors for inpatient hospital services.

II. Inpatient Hospital Update for FY 2021

A. Proposed FY 2021 Inpatient Hospital Update

As discussed in section IV.B. of the preamble to this proposed rule, for FY 2021, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act and a reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful electronic health record (EHR) users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then subject to an adjustment based on changes in economy-wide productivity (the multifactor productivity (MFP) adjustment). Section 1886(b)(3)(B)(xi) of the Act, as added by section 3401(a) of the Affordable Care Act, states that application of the MFP adjustment may result in the applicable percentage increase being less than zero. (We note that section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.)

We note that, in compliance with section 404 of the MMA, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38158 through 38175), we replaced the FY 2010-based IPPS operating and capital market baskets with the rebased and revised 2014-based IPPS operating and capital market baskets effective beginning in FY 2018.

In this FY 2021 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to base the proposed FY 2021 market basket update used to determine the applicable percentage increase for the IPPS on IGI's fourth quarter 2019 forecast of the 2014-based IPPS market basket rate-of-increase with historical data through third quarter 2019, which is estimated to be 3.0 percent. In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section IV.B. of the preamble of this FY 2021 IPPS/LTCH PPS proposed rule, based on IGI's fourth quarter 2019 forecast, we are proposing a MFP adjustment of 0.4 percent for FY 2021. We also are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2021 market basket update and MFP adjustment for the final rule.

Therefore, based on IGI's fourth quarter 2019 forecast of the 2014-based IPPS market basket and the MFP adjustment, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), we are proposing four possible applicable percentage increases that could be applied to the standardized amount, as shown in the following table.

FY 2021	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Proposed Market Basket Rate-of-Increase	3.0	3.0	3.0	3.0
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.75	-0.75
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-2.25	0	-2.25
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.4	-0.4	-0.4	-0.4
Proposed Applicable Percentage Increase Applied to Standardized Amount	**2.6**	**0.35**	**1.85**	**-0.4**

B. Proposed Update for SCHs and MDHs for FY 2021

Section 1886(b)(3)(B)(iv) of the Act provides that the FY 2021 applicable percentage increase in the hospital-specific rate for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Under current law, the MDH program is effective for discharges through September 30, 2022, as discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41429 through 41430).

As previously mentioned, the update to the hospital specific rate for SCHs and MDHs is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, depending on whether a hospital submits quality data and is a meaningful EHR user, we are proposing the same four possible applicable percentage increases in the preceding table for the hospital-specific rate applicable to SCHs and MDHs.

C. Proposed FY 2021 Puerto Rico Hospital Update

As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56939), prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. Section 601 of Public Law 114–113 amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to make an update to the Puerto Rico standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the same update to the national standardized amount discussed under section IV.B.1. of the preamble of this proposed rule. Accordingly, for FY 2021, we are proposing to establish an applicable percentage increase of 2.6 percent to the standardized amount for hospitals located in Puerto Rico.

D. Proposed Update for Hospitals Excluded From the IPPS for FY 2021

Section 1886(b)(3)(B)(ii) of the Act is used for purposes of determining the percentage increase in the rate-of-increase limits for children's hospitals, cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and America Samoa). Section 1886(b)(3)(B)(ii) of the Act sets the percentage increase in the rate-of-increase limits equal to the market basket percentage increase. In accordance with § 403.752(a) of the regulations, RNHCIs are paid under the provisions of § 413.40, which also use section 1886(b)(3)(B)(ii) of the Act to update the percentage increase in the rate-of-increase limits. Currently, children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa are among the remaining types of hospitals still paid under the reasonable cost methodology, subject to the rate-of-increase limits. In addition, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals (described in § 412.22(i) of the regulations) also are subject to the rate-of-increase limits. As discussed in section VI. of the preamble of this proposed rule, in the FY 2018 IPPS/LTCH PPS final rule, we finalized the use of the percentage increase in the 2014-based IPPS operating market basket to update the target amounts for children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2018 and subsequent fiscal years. In addition, as discussed in section IV.B. of the preamble of this proposed rule, the update to the target amount for extended neoplastic disease care hospitals for FY 2021 would be the percentage increase in the 2014-based IPPS operating market basket. Accordingly, for FY 2021, the rate-of-increase percentage to be applied to the target amount for these children's hospitals, cancer hospitals, RNHCIs, extended neoplastic disease care hospitals, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa would be the FY 2021 percentage increase in the 2014-based IPPS operating market basket. For this proposed rule, the current estimate of the IPPS operating market basket percentage increase for FY 2021 is 3.0 percent.

E. Proposed Update for LTCHs for FY 2021

Section 123 of Public Law 106–113, as amended by section 307(b) of Public Law 106–554 (and codified at section 1886(m)(1) of the Act), provides the statutory authority for updating payment rates under the LTCH PPS.

As discussed in section V.A. of the Addendum to this proposed rule, we are proposing to update to the LTCH PPS standard Federal payment rate for FY 2021 by 2.5 percent, consistent with section 1886(m)(3) of the Act which provides that any annual update be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (that is, the MFP adjustment). Furthermore, in accordance with the LTCHQR Program under section 1886(m)(5) of the Act, we are proposing to reduce the annual update to the LTCH PPS standard Federal rate by 2.0 percentage points for failure of a LTCH to submit the required quality data. Accordingly, we are proposing to establish an update factor of 1.025 in determining the LTCH PPS standard Federal rate for FY 2021. For LTCHs that fail to submit quality data for FY 2021, we are proposing an annual update to the LTCH PPS standard Federal rate of 0.5 percent (that is, the proposed annual update for FY 2021 of 2.5 percent less 2.0 percentage points for failure to submit the required quality data in accordance with section 1886(m)(5)(C) of the Act and our rules) by applying a proposed update factor of 1.005 in determining the LTCH PPS standard Federal rate for FY 2021. (We note that, as discussed in section VII.D. of the preamble of this proposed rule, the proposed update to the LTCH PPS standard Federal payment rate of 2.5 percent for FY 2021 does not reflect any proposed budget neutrality factors.)

III. Secretary's Recommendations

MedPAC is recommending an inpatient hospital update of 2.0 percent. Consistent with current law, depending on whether a hospital submits quality data and is a meaningful EHR user, we are recommending

the four applicable percentage increases to the standardized amount listed in the table under section II. of this Appendix B. We are recommending that the same applicable percentage increases apply to SCHs and MDHs.

In addition to making a recommendation for IPPS hospitals, in accordance with section 1886(e)(4)(A) of the Act, we are recommending update factors for certain other types of hospitals excluded from the IPPS. Consistent with our policies for these facilities, we are recommending an update to the target amounts for children's hospitals, cancer hospitals, RNHCIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa and extended neoplastic disease care hospitals of 3.0 percent.

For FY 2021, consistent with policy set forth in section VII. of the preamble of this proposed rule, for LTCHs that submit quality data, we are recommending an update of 2.5 percent to the LTCH PPS standard Federal rate. For LTCHs that fail to submit quality data for FY 2021, we are recommending an annual update to the LTCH PPS standard Federal rate of 0.5 percent.

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

In its March 2020 Report to Congress, MedPAC assessed the adequacy of current payments and costs, and the relationship between payments and an appropriate cost base. MedPAC recommended an update to the hospital inpatient rates by 2 percent with the difference between this and the update amount specified in current law to be used to increase payments under MedPAC's proposed Medicare quality program, the ''Hospital Value Incentive Program (HVIP).'' MedPAC stated that together, these recommendations, paired with the recommendation to eliminate the current hospital quality program incentives, would increase hospital payments by increasing the base payment rate and by increasing the average rewards hospitals receive under MedPAC's proposed Medicare HVIP. We refer readers to the March 2020 MedPAC report, which is available for download at *www.medpac.gov*, for a complete discussion on these recommendations.

Response: With regard to MedPAC's recommendation of an update to the hospital inpatient rates equal to 2 percent, with the remainder of the 2.6 percent to be used to fund its recommended Medicare HVIP, section 1886(b)(3)(B) of the Act sets the requirements for the FY 2021 applicable percentage increase. Therefore, consistent with the statute, we are proposing an applicable percentage increase for FY 2021 of 2.6 percent, provided the hospital submits quality data and is a meaningful EHR user consistent with these statutory requirements. Furthermore, we appreciate MedPAC's recommendation concerning a new HVIP. We agree that continual improvement motivated by quality programs is an important incentive of the IPPS.

We note that, because the operating and capital payments in the IPPS remain separate, we are continuing to use separate updates for operating and capital payments in the IPPS. The proposed update to the capital rate is discussed in section III. of the Addendum to this proposed rule.

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